the Science behind

The Magic of Ayurveda

Clinical studies on medicinal plants included in the polyherbal formulation JVN-8





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The Science Behind the Magic of Ayurveda: Clinical studies on medicinal plants included in the polyherbal formulation JVN-8

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2015
Rajasthan State Medicinal Plants Board
AYUSH Bhawan, Jaipur
Rajasthan

RSMPB Occasional Paper No. 1/2015

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Caution: This is purely an academic document. Herbal medicines should be used only in consultation with an Ayurvedic doctor. यह केवल एक शैक्षिक दस्तावेज है। किसी भी जड़ी-बूटी का प्रयोग आयुर्वेदिक डॉक्टर के परामर्श से ही करें!

Conflict of interests statement: Sanjay Dixit, IAS is the Principal Secretary, Ayurveda and Indian Medicine in Government of Rajasthan. He also holds the charge of Vice Chancellor, Rajasthan Ayurved University, Jodhpur. During his tenure major initiatives have been taken for promotion of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy) in Rajasthan. Dr. Deep Narayan Pandey, IFS is the Member Secretary, Rajasthan State Medicinal Plants Board, Jaipur. He also holds the additional charge of Director, Unani Medicine, Rajasthan. During his tenure the RSMPB has taken several innovative initiatives to promote conservation and farming of medicinal plants in Rajasthan. Both the authors state that they do not have any competing financial interests in relation to either the Ayurvedic polyherbal medicine they developed (i.e., JVN-8) or this paper. Following the principles of reverse pharmacology, some patients may be taking the drug JVN-8. In this context, both the authors also declare that they have not benefitted financially from either the patients being treated with JVN-8 or the volunteers who may be participating in clinical trial of the drug. Both authors have contributed equally for development of JVN-8 as well as writing this report.

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Introduction

Age-related onset of pathogenesis presents a substantial healthcare and economic challenge before the global society. The world is headed to a situation in which by the year 2050 there will be the same number of old as young, with 2 billion people aged 60 or over and another 2 billion under age 15, each group accounting for 21% of the world's population[1]. It is well known that 63% of all deaths worldwide currently emanate from non-communicable diseases, mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. These diseases pose a rising and substantial economic burden both in terms of healthcare costs and lost workdays. For example, with respect to cardiovascular disease, chronic respiratory disease, cancer, diabetes and mental health, studies suggest a cumulative output loss of US$ 47 trillion over the next two decades. This loss equals 75% of global GDP in 2010 (US$ 63 trillion). It also represents enough money that can eradicate two-dollar-a-day poverty among the 2.5 billion who remained poor for more than half a century[2].

Global community is now trying to find out the sustainable solutions to age-related onset of fatal diseases across various healthcare systems. Accordingly, we posed a question to ourselves; if Ayurveda, the world's most comprehensive, personalized, holistic and sustainable healthcare system can provide solutions to substantially delay the age-related pathogenesis? In other words, if you do not suffer from a critical illness today, is it possible to remain healthy for substantial period of life or is it possible to increase health span? We hypothesized that the answer may be, yes.

Some caveats need to be made clear upfront. First, while the drug we intended to develop is aimed at addressing the challenges of advancing age, these efforts are not to be termed as anti-aging. The drug is not intended to increase the life-span; rather it is aimed at extending the health span (i.e., healthy and disease-free years in our life). Second, the dream is to develop a drug accessible to rich and poor alike, meaning thereby that it should fulfil both the criteria of cost as well as ease of production. Thus, crude as well as extract formulation have been developed. As per the current market rates the daily dose of the formulation developed as

natural crude form costs INR 3.00. The extraction in the form of capsules costs about INR 10.00 per day.

After identifying relevant major illnesses such as cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, we studied the original ancient Ayurveda texts including the *Brahattrai* i.e., *Charaka Samhita*, *Sushruta Samhita* and Vagbhatta's *Asthanga Haridayam*. *Charaka Samhita* is one of the two foundational texts of Ayurveda that has survived since the period of 900 BCE - 600 BCE. This helped us to identify a range of candidate herbs indicated to address the identified diseases. Next, we assembled a large database of scientific research on Ayurveda, phytomedicine and ethnomedicine published worldwide for each of the clinical condition relevant to delaying the age-related pathogenesis. With the help of this database we worked backward and forward to identify another set of candidate herbs that have shown promise in addressing the identified challenges. A comparison and concordance yielded a set of species that were common to both lists. For each of the medicinal plant species, we scanned the scientific literature for *in vitro* and *in vivo* studies and clinical research (clinical cases, clinical studies, and diversity of clinical trials). Majority of these studies have followed modern scientific methodologies but clinical case studies conducted and published by Ayurveda doctors were also included. Relevant clinical research from Unani and Siddha healthcare systems were also considered. Through these scientific studies the efficacy and safety of each candidate species was assessed.

The formulation, named as JVN-8, contains 8 species of medicinal plants in specific proportion: *Terminalia bellirica* (Gaertn.) Roxb., *Terminalia chebula* Retz., *Phyllanthus emblica* Gaertn, *Piper longum* L., *Piper nigrum* L., *Zingiber officinale* Roscoe, *Tinospora cordifolia* (Thunb.) Miers, and *Withania somnifera* (L.) Dunal. Interestingly, these are among the most important medicinal plants in AYUSH system of medicines. Many of these species are also extensively grown in herbal home gardens across India.

As noted above, the medicinal plants identified here have been in use since ancient times and the safety has been extensively studied. Thus a "reverse pharmacology" approach was followed. Since safety of the identified individual medicinal plants has already been established by ethnomedicinal use, long-term Ayurvedic use, and clinical studies of drugs containing one or more of the identified candidate set of species, polyherbal formulation named JVN-8 was subjected to a clinical study among a small number of volunteers.

Fresh interpretation of available *in vitro* and *in vivo* studies, clinical trials on the herbs included in this polyherbal formulation, and a nonrandomized, uncontrolled, single group, open-label observational clinical study of the formulation for 90 days among 18 human volunteers suggests that JVN-8 can be a cost-effective, safe and useful drug in a large number of conditions of clinical relevance. These findings shall be reported elsewhere in due course.

As further largescale trial of this polyherbal formulation shall be useful, in the next section we present clinical studies on various Ayurvedic drugs and phytomedicines that contain one or more of the medicinal plants included in the polyherbal formulation, JVN-8. The bibliography provides evidence in the form of numerous studies on efficacy and safety of herbs in JVN-8. It also helped us in taking the reverse pharmacological approach. The clinical studies can draw on this literature to inform further studies. As there is no unequivocally accepted biomarker for geriatric problems, efficacy of JVN-8 can only be judged by an unusual yardstick, i.e., whether it could delay the development of several conditions and diseases whose incidence increases dramatically with age (delay in the onset of age-related pathologies): cardiovascular disease, cancer, diabetes, chronic respiratory diseases, and cognitive decline etc. Similar approach is being followed by researchers involved in an interesting clinical trial that is likely to cost up to US$50 million to test if the drug Metformin (which is already in use for treatment of diabetes worldwide) is capable of extending human health span[3]. We hope that the document shall be useful for conducting *in vitro* and *in vivo* studies and robust clinical trials (i.e., randomized, double-blind, placebo-controlled, multi-centre, crossover trials) in future.

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1. Harper, S., Economic and social implications of aging societies. *Science,* 2014, **346**, 587-591.

2. Bloom, D.E., Cafiero, E., Jané-Llopis, E., Abrahams-Gessel, S., Bloom, L.R., Fathima, S., Feigl, A.B., Gaziano, T., Hamandi, A., Mowafi, M., O'Farrell, D., Ozaltin, E., Pandya, A., Prettner, K., Rosenberg, L., Seligman, B., Stein, A.Z., Weinstein, C. and Weiss, J., The global economic burden of noncommunicable diseases. Program on the Global Demography of Aging Available at https://ideas.repec.org/p/gdm/wpaper/8712.html#cites.

3. Hall, S.S., A trial for the ages. *Science,* 2015, **349**, 1274-1278.

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Clinical studies on medicinal plants included in the polyherbal formulation JVN-8©™

1. Abdel-Moneim, A., B. M. Morsy, A. M. Mahmoud, M. A. Abo-Seif and M. I. Zanaty (2013). "**Beneficial therapeutic effects of *Nigella sativa* and/or *Zingiber officinale* in HCV patients in Egypt**." EXCLI Journal **12**: 943-955.

Hepatitis C is a major global health burden and Egypt has the highest prevalence of hepatitis C virus (HCV) worldwide. The current study was designed to evaluate the beneficial therapeutic effects of ethanolic extracts of Nigella sativa, ***Zingiber officinale*** and their mixture in Egyptian HCV patients. Sixty volunteer patients with proven HCV and fifteen age matched healthy subjects were included in this study. Exclusion criteria included patients on interferon alpha (IFN-α) therapy, infection with hepatitis B virus, drug-induced liver diseases, advanced cirrhosis, hepatocellular carcinoma (HCC) or other malignancies, blood picture abnormalities and major severe illness. Liver function enzymes, albumin, total bilirubin, prothrombin time and concentration, international normalized ratio, alpha fetoprotein and viral load were all assessed at baseline and at the end of the study. Ethanolic extracts of Nigella sativa and *Zingiber officinale* were prepared and formulated into gelatinous capsules, each containing 500 mg of Nigella sativa and/or *Zingiber officinale*. Clinical response and incidence of adverse drug reactions were assessed initially, periodically, and at the end of the study. Both extracts as well as their mixture significantly ameliorated the altered viral load, alpha fetoprotein, liver function parameters; with more potent effect for the combined therapy. In conclusion, administration of *Nigella sativa* and/or *Zingiber officinale* ethanolic extracts to HCV patients exhibited potential therapeutic benefits via decreasing viral load and alleviating the altered liver function, with more potent effect offered by the mixture.

2. Adhikari, A., S. Biswas, R. Raman De, A. Mitra, J. Hazra and P. K. Debnath (2013). "**Role of Imunomet in upper respiratory tract disorders: A randomized double blind placebo controlled clinical trial.**" Indian Journal of Traditional Knowledge **12**(2): 281-283.

Upper respiratory tract disorders comprise 87.5% of total acute respiratory morbidity in children in India. This has become a major community health problem. The symptoms are often self limiting and many a time caused by viruses, however, recurrent attacks may lead to distinct morbidity. This study was conducted in hospital outpatient department on children who have been attending at frequent interval with complaints of sore throat, pharyngitis, tonsillitis. They were administered Imunomet syrup or tablet (a multiherbal formulation contains *Asparagus racemosus*, ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***), *Glycyrrhiza glabra*) for a period of 8 weeks. At the end of the treatment, about 84% patients responded well to treatment and 16% patients had fair response to treatment. None of the patients showed any adverse reaction to treatment. The syrup was found to be palatable.

3. Adhvaryu, M. R., N. M. Reddy and B. C. Vakharia (2008). "**Prevention of hepatotoxicity due to anti tuberculosis treatment: A novel integrative approach.**" World Journal of Gastroenterology **14**(30): 4753-4762.

Aim was to evaluate the ability of *Curcuma longa* (CL) and ***Tinospora cordifolia*** (TC) formulation to prevent anti-tuberculosis (TB) treatment (ATT) induced hepatotoxicity. Patients with active TB diagnosis were randomized to a drug control group and a trial group on drugs plus an herbal formulation. Isoniazid, rifampicin, pyrazinamide and ethambutol for first 2 mo followed by continuation phase therapy excluding Pyrazinamide for 4 mo comprised the anti-tuberculous treatment. Curcumin enriched (25%) CL and a hydro-ethanolic extract enriched (50%) TC 1 g each divided in two doses comprised the herbal adjuvant. Hemogram, bilirubin and liver enzymes were tested initially and monthly till the end of study to evaluate the result. Results: Incidence and severity of hepatotoxicity was significantly lower in trial group (incidence: 27/192 vs 2/316, P < 0.0001). Mean aspartate transaminase (AST) (195.93 ± 108.74 vs 85 ± 4.24, P < 0.0001), alanine transaminase (ALT) (75.74 ± 26.54 vs 41 ± 1.41, P < 0.0001) and serum bilirubin (5.4 ± 3.38 vs 1.5 ± 0.42, P < 0.0001). A lesser sputum positivity ratio at the end of 4 wk (10/67 vs 4/137, P = 0.0068) and decreased incidence of poorly resolved parenchymal lesion at the end of the treatment (9/152 vs 2/278, P = i0.0037) was observed. Improved patient compliance was indicated by nil drop-out in trial vs 10/192 in control group (P < 0.0001). The herbal formulation prevented hepatotoxicity significantly and improved the disease outcome as well as patient compliance without any toxicity or side effects.

4. Agrawal, A. K., D. M. Tripathi, R. Sahai, N. Gupta, R. P. Saxena, A. Puri, M. Singh, R. N. Misra, C. B. Dubey and K. C. Saxena (1997). "**Management of Giardiasis by a herbal drug 'Pippali Rasayana': A clinical study.**" Journal of Ethnopharmacology **56**(3): 233-236.

Pippali Rasayana (PR), an Indian ayurvedic drug prepared from Palash (*Butea monosperma* (Lamk) Kuntze; Leguminaceae) and Pippali (***Piper longum*** L.; Piperaceae), was administered at a dose of 1 g p.o. three times daily for a period of 15 days to patients (25 treated, 25 placebo controls) suffering from giardiasis with clinical signs and symptoms, and stools positive for trophozoites/cysts of Giardia lamblia. After 15 days of drug treatment there was a complete disappearance of G. lamblia (trophozoites/cysts) from the stools of 23 out of 25 patients. General signs and symptoms of ill health and abdominal discomfort, presence of mucus, pus cells and RBCs were significantly reduced. There was a marked improvement in the clinical and haematological profile of the patients. Spontaneous recovery in 20% cases was recorded in placebo controls.

5. Ahmed, A. O., J. S. Tripathi and I. S. Gambhir (2013). "**Comparative clinical evaluation of an ayurvedic regimen in the management of senile dementia.**" International Journal of Research in Ayurveda and Pharmacy **4**(3): 307-311.

An enhanced life expectancy in developed countries has been accompanied by an increased number of people suffering from age-associated dementia. Senile dementia is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, without any impairment in consciousness. Prevalence rates for senile dementia

increase essentially with advancing age. The prevalence rate rises to 54.8% in individuals above 95 years of age. So far, efforts to find a cure for Alzheimer Disease (AD) have been disappointing, and the drugs currently available to treat the disease address only its symptoms and with limited effectiveness. Present study was design to see the efficacy of Saraswata ghrita (includes ***Trikatu*: *Zingiber officinale, Piper longum, Piper nigrum***) along with Shirobasti on Senile dementia. A total number of 34 patients of Senile dementia were recruited by using ICD- 10 criteria of Dementia and MMSE scores and randomly divided in to two groups. Alzheimer's disease assessment scale (cognitive subscale) has been used to evaluate the clinical condition of the patients of Senile dementia. After completion of treatment Saraswata ghrita along with Shirobasti shows statistically significant results on clinical and neuro-cognitive parameters.

6. Altman, R. D. and K. C. Marcussen (2001). "**Effects of a ginger extract on knee pain in patients with osteoarthritis.**" Arthritis and Rheumatism **44**(11): 2531-2538.

Objective was to evaluate the efficacy and safety of a standardized and highly concentrated extract of 2 ginger species, ***Zingiber officinale*** and *Alpinia galanga* (EV.EXT 77), in patients with osteoarthritis (OA) of the knee. Two hundred sixty-one patients with OA of the knee and moderate-to-severe pain were enrolled in a randomized, double-blind, placebocontrolled, multicenter, parallel-group, 6-week study. After washout, patients received ginger extract or placebo twice daily, with acetaminophen allowed as rescue medication. The primary efficacy variable was the proportion of responders experiencing a reduction in "knee pain on standing," using an intent-to-treat analysis. A responder was defined by a reduction in pain of ≥15 mm on a visual analog scale. In the 247 evaluable patients, the percentage of responders experiencing a reduction in knee pain on standing was superior in the ginger extract group compared with the control group (63% versus 50%; P = 0.048). Analysis of the secondary efficacy variables revealed a consistently greater response in the ginger extract group compared with the control group, when analyzing mean values: reduction in knee pain on standing (24.5 mm versus 16.4 mm; P = 0.005), reduction in knee pain after walking 50 feet (15.1 mm versus 8.7 mm; P = 0.016), and reduction in the Western Ontario and McMaster Universities osteoarthritis composite index (12.9 mm versus 9.0 mm; P = 0.087). Change in global status and reduction in intake of rescue medication were numerically greater in the ginger extract group. Change in quality of life was equal in the 2 groups. Patients receiving ginger extract experienced more gastrointestinal (GI) adverse events than did the placebo group (59 patients versus 21 patients). GI adverse events were mostly mild. A highly purified and standardized ginger extract had a statistically significant effect on reducing symptoms of OA of the knee. This effect was moderate. There was a good safety profile, with mostly mild GI adverse events in the ginger extract group.

7. Ambiye, V. R., D. Langade, S. Dongre, P. Aptikar, M. Kulkarni and A. Dongre (2013). "**Clinical evaluation of the spermatogenic activity of the root extract of Ashwagandha (*Withania somnifera*) in oligospermic males: A pilot study.**" Evidence-based Complementary and Alternative Medicine ID 571420.

Ashwagandha (***Withania somnifera***) has been described in traditional Indian Ayurvedic medicine as an aphrodisiac that can be used to treat male sexual

dysfunction and infertility. This pilot study was conducted to evaluate the spermatogenic activity of Ashwagandha root extract in oligospermic patients. Forty-six male patients with oligospermia (sperm count < 20 million/mL semen) were enrolled and randomized either to treatment (n = 21) with a full-spectrum root extract of Ashwagandha (675 mg/d in three doses for 90 days) or to placebo (n = 25) in the same protocol. Semen parameters and serum hormone levels were estimated at the end of 90-day treatment. There was a 167% increase in sperm count (9.59 ± 4.37 × 10^6/mL to 25.61 ± 8.6 × 10^6/mL), 53% increase in semen volume (1.74 ± 0.58 mL to 2.76 ± 0.60 mL), and 57% increase in sperm motility (18.62 ± 6.11% to 29.19 ± 6.31%) on day 90 from baseline. The improvement in these parameters was minimal in the placebo-treated group. Furthermore, a significantly greater improvement and regulation were observed in serum hormone levels with the Ashwagandha treatment as compared to the placebo. The present study adds to the evidence on the therapeutic value of Ashwagandha (*Withania somnifera*), as attributed in Ayurveda for the treatment of oligospermia leading to infertility.

8. Anagha, D. N., MythreyR.C and G. Hegde (2013). "**Clinical study on the efficacy of amritadi ghrita and kutaja sooryapaka taila in the management of vicharchika vis-à-vis eczema.**" International Journal of Research in Ayurveda and Pharmacy **4**(6): 820-824.

Vicharchika is explained as one among Ekadasha Kshudra Kustha. The clinical features of vicharchika like Kandu, Pidaka, Shyavavarnata, Srava, Rookshata, Daha, Raji, and Vedana are very much similar with the features of Eczema. This is an inflammatory response produced by various internal and external factors. To manage such inflammatory condition of the skin, shamana chikitsa, in the form of bahya and abhyantara sneha prayoga was planned in order to have a safe and effective result in treating Vicharchika vis-à-vis Eczema. The objective of this study was, to evaluate the efficacy of Amritadi Ghrita as Shamana sneha along with the external application of Kutaja Sooryapaka Taila in the management of Vicharchika vis-à-vis Eczema. It is an observational clinical study with pre, mid and post test design where 30 patients of Vicharchika vis-à-vis Eczema were randomly selected and subjected to deepana and pachana with ***Trikatu*** choorna (***Zingiber officinale, Piper longum, Piper nigrum***) administered in a dose of 2 g thrice daily before food with ushnodaka, until nirama lakshanas were observed. Shamana snehapana by Amritadi Ghritha was advised in the dose of 30 ml, in empty stomach at annakala for 30 days along with external application of Kutajasooryapaka Taila twice a day after thoroughly cleaning the affected area of the skin with lukewarm water. Pathya ahara and Vihara were advised throughout the course of the study. In the present study, results obtained with respect to all the parameters were statistically highly significant with 'P' value of 0.000. Overall assessment showed marked relief in 20 patients, moderate relief in 6 patients followed by complete relief in 4 patients. Significant results in reduction of all the parameters i.e. Kandu (87.5 %), Pidaka (85.8 %), Srava (60.83 %), Rookshata (60.83 %) and Vaivarnyata (89.16 %) were found. Hence Amritadi Ghrita as Shamana sneha along with the external application of Kutaja Sooryapaka Taila was found to be very effective in the management of Vicharchika vis-à-vis Eczema.

9. Andallu, B. and B. Radhika (2000). "**Hypoglycemic, diuretic and hypocholesterolemic effect of Winter cherry (*Withania somnifera*, Dunal) root**." Indian Journal of Experimental Biology **38**(6): 607-609.

Hypoglycemic, diuretic and hypocholesterolemic effects of roots of ***Withania somnifera*** (ashvagandha) were assessed on human subjects. Six mild NIDDM subjects and six mild hypercholesterolemic subjects were treated with the powder of roots of *W. somnifera* for 30 days. Suitable parameters were studied in the blood and urine samples of the subjects along with dietary pattern before and at the end of treatment period. Decrease in blood glucose was comparable to that of an oral hypoglycemic drug. Significant increase in urine sodium, urine volume, significant decrease in serum cholesterol, triglycerides, LDL (low density lipoproteins) and VLDL (very low density lipoproteins) cholesterol were observed indicating that root of *W. somnifera* is a potential source of hypoglycemic, diuretic and hypocholesterolemic agents. Clinical observations revealed no adverse effects.

10. Andrade, C., A. Aswath, S. Chaturvedi, M. Srinivasa and R. Raguram (2000). "**A double-blind, placebo-controlled evaluation of the anxiolytic efficacy of an ethanolic extract of *Withania somnifera*.**" Indian Journal of Psychiatry **42**(3): 295-301.

A double-blind, placebo-controlled study was conducted to evaluate the efficacy an ethanolic extract of Aswagandha (***Withania somnifera***), in patients with ICD-10 anxiety disorders. The sample comprised 39 subjects, of whom 20 received the drug and 19 received placebo. The two groups were sociodemographically and clinically similar at baseline. At 2 and 6 weeks follow-up, data from approximately 85% of patients in each group were available for analysis. Statistical trends favouring the drug were observed at both time points. At 6 weeks, significantly more patients met a priori response criteria in the drug group (88.2%) as compared with the placebo group (50%). The drug was well-tolerated and did not occasion more adverse effects than did placebo. It is concluded that this ethanolic extract of *Withania somnifera* has useful anxiolytic potential and merits further investigation.

11. Angadi, S. S. and S. T. Gowda (2014). "**Management of Vyanga (facial melanosis) with Arjuna Twak Lepa and Panchanimba Churna.**" AYU **35**(1): 50-53.

Vyanga is one of the Kshudraroga, characterized by the presence of Niruja (painless) and Shavavarna Mandalas (bluish-black patches) on face. It is one of the most common diseases as regards the face is concerned. On the basis of clinical features, it can be compared with facial melanosis, one of the hyper pigmented disorders. Drugs with Rakta Prasadaka, Twak Prasadaka and Varnyakara properties are helpful in the management of Vyanga, that pacifies aggregated Doshas and help in Raktashodhana (blood purification). Aim: To evaluate the efficacy of Arjunatwak Lepa and Panchanimba Churna in Vyanga. Materials and Methods: In this study, the trial drugs used were Arjunatwak Churna for Lepa (tropical application) and Panchanimba Churna for oral administration. Ingredients of Panchanimba Churna are as follows: Nimba (*Azadirachta indica* A. Juss., Pippali (***Piper longum*** Linn.), Maricha (***Piper nigrum*** Linn.), Chitraka (*Plumbago zeylanica* Linn.), Haritaki (***Terminalia chebula*** (Gareth) Roxb.), Amalaki (***Emblica officinalis*** Gaerth.), Bakuchi (*Psoralia corylifolia* Linn.), Gokshura (*Tribulus terristris* Linn.), Vidanga (*Embelia ribes* Burm.), Araghwada (*Cassia fistula* Linn.), Haridra (*Curcuma longa* Linn.), Chakramarda (*Cassia tora* Linn.),

Shunti (***Zingiber officinale*** Roxb.), Bhallataka (*Semicarpus anacardium* Linn.), Louha bhasma, Sharkara (*Saccharum officinarum* Linn.), Bhringaraja (*Eclipta alba* Hassk.), Khadira (*Acacia catechu* Willd.). A total 30 patients of Vyanga were selected from outpatient department and inpatient department of Shalakya Tantra Department and allotted randomly in two groups. In group-A, the patients were treated with external application of Arjunatwak Churna and Madhu for 21 days, while in group-B, patients received Panchanimba Churna orally for 21 days in addition to Arjunatwak Churna for Lepa. Effect of therapy on chief complaint i.e., bluish-black pigmentation in Group A was 60% relief, while in Group B 80% relief was found. The clinical study has shown that combined therapy gives better results than topical treatment.

12. Antony, B., M. Benny and T. N. B. Kaimal (2008). "**A pilot clinical study to evaluate the effect of *Emblica officinalis* extract (Amlamax™) on markers of systemic inflammation and dyslipidemia.**" Indian Journal of Clinical Biochemistry **23**(4): 378-381.

Emblica officinalis Gaertn., commonly known as the Indian gooseberry or "Amla", has been used as health food for centuries in India and other Asian countries. The biological effects of amla have been attributed to the antioxidant properties of the low-molecular weight hydrolysable tannins present in the fruit. Amlamax™ is a purified, standardized, dried extract of amla containing about 35% galloellagi tannins along with other hydrolysable tannins. Earlier studies on rabbits showed significant reduction in total cholesterol and triglycerides as well as increase in HDL. The present study extends these results to human volunteers. Two doses of the extract were evaluated - 500 mg and 1000 mg per day for 6 months. Blood samples were collected at the 3 rd and 6 th months showed reduction in total and LDL cholesterols and enhancement of beneficial HDL cholesterol. In addition, blood CRP levels, a marker for inflammation, were also significantly reduced. Since dyslipidemia and inflammation are the two major components of cardiovascular diseases, the present results must be considered encouraging and indicate the potential of AmlamaxTM in the management of heart diseases.

13. Arslan, M. and L. Ozdemir (2015). "**Oral Intake of ginger for chemotherapy-induced nausea and vomiting among women with breast cancer.**" Clinical Journal of Oncology Nursing **19**(5): E92-E97.

Chemotherapy-induced nausea and vomiting (CINV) is among the most common and distressing symptoms experienced by patients receiving cancer treatment. Nurses play a substantial role in the prevention and management of CINV. Ginger (***Zingiber officinale*** Roscoe) is often advocated as beneficial for nausea and vomiting. Whether the herb is truly efficacious for this condition is, however, still a matter of debate. This experimental randomized, controlled trial was done to assess the effect of ginger on chemotherapy-related nausea and vomiting. All patients in the study (N = 60) received standard antiemetic drugs. The patients in the study group (n = 30) also received oral ginger for the first three days of the chemotherapy cycle. No intervention was performed in the control group (n = 30) except for the routine antiemetic treatment. Nausea severity and the number of vomiting and retching episodes were measured four times each day for the first five days of the chemotherapy cycle in the patient diary. Nausea severity was evaluated using a numeric scale ranging from 0 (no nausea) to 10 (very severe nausea). Nausea severity

and the number of vomiting episodes were significantly lower in the intervention group than in the control group ($p > 0.05$). However, the change in the number of retching episodes between the intervention and control groups was not statistically significant ($p > 0.05$).

14. Aspalli, S., V. S. Shetty, M. V. Devarathnamma, G. Nagappa, D. Archana and P. Parab (2014). "**Evaluation of antiplaque and antigingivitis effect of herbal mouthwash in treatment of plaque induced gingivitis: A randomized, clinical trial.**" Journal of Indian Society of Periodontology **18**(1): 48-52.

Ayurvedic drugs have been used since ancient times to treat diseases including periodontal diseases. Oral rinses made from ayurvedic medicines are used in periodontal therapy to control bleeding and reduce inflammation. The aim of this clinical study is to verify the efficacy of herbal mouthwash containing Pilu, Bibhitaka (***Terminalia bellirica***), Nagavalli, Gandhapura taila, Ela, Peppermint satva, and Yavani satva on reduction of plaque and gingivitis. A total of 100 volunteers with clinical signs of mild to moderate gingivitis were selected and assigned to Group A (only scaling done) and Group B (scaling along with the use of herbal mouthwash). After recording the clinical parameters, the patients were instructed to use herbal mouthwash 15 ml for 30 s twice daily after food in Group B and oral hygiene instructions were given to all patients. Plaque and gingivitis assessment were carried out using the plaque index (Silness nd Loe, 1964), Gingival index (Loe And Silness, 1963), Gingival bleeding index (Ainamo and Bay, 1975) at baseline and at 21 days of the herbal mouthwash use. Statistically analysis was carried out using the student's t-test for normally distributed data and Wilcoxson test or Mann-Whitney U-test for skewed data. These results showed that herbal mouthwash was effective in treatment of plaque induced gingivitis in Group B when compared with the Group A. Herbal mouthwash is effective in treatment of plaque induced gingivitis and can be effectively used as an adjunct to mechanical therapy with lesser side-effects.

15. Atashak, S., M. A. Azarbayjani, M. Piri and A. Jafari (2012). "**Effects of combination of long - Term ginger consumption and resistance training on lipid peroxidation and insulin resistance in obese men.**" Journal of Medicinal Plants **11**(42): 179-188.

The present study investigated the effects of long-term ginger (***Zingiber officinale***) consumption and progressive resistance training on lipid per oxidation and insulin resistance in obese men. In a randomized double-blind design, 32 obese men (BMI≥ 30) were assigned in to one of four groups: a Placebo (PL,n=8), Ginger group, that consumed 1 gr ginger/d for 10 wk (GI,n=8), resistance training plus Placebo (PLRT,n=8), and 1gr ginger plus resistance exercise (GIRT, n=8). Progressive resistance training was performed three days per week for 10 weeks and included 8 exercises. At baseline and after 10 weeks venous blood samples were obtained from the antecubital vein, and Malondialdehyde (MDA) as an indicator of lipid peroxidation, pectrophotometrically were assayed by measurement of TBARS assay. Moreover, insulin resistance was determined using a homeostasis model assessment (HOMA-IR). Two-way ANOVA were used in the statistical analysis. Results: After 10 weeks of intervention, authors observed a significant decrease for MDA concentration in all groups exception Placebo group ($P<0.05$). Moreover, significant decreases in the

mean values of insulin resistance were observed in CIRT and PLRT groups (P<0.05). While it remained unchanged in GI and PL groups (p>0.05): Therefore, according to this results it can be said, that, long term ginger consumption and resistance training has been an effective therapeutic devise to favorable changes in lipid peroxidation and insulin resistance in obese men.

16. Atashak, S., M. Peeri, M. A. Azarbayjani and S. R. Stannard (2014). "**Effects of ginger (*Zingiber officinale* Roscoe) supplementation and resistance training on some blood oxidative stress markers in obese men.**" Journal of Exercise Science and Fitness **12**(1): 26-30.

Excessive adiposity increases oxidative stress, and thus may play a critical role in the pathogenesis and development of obesity-associated comorbidities, in particular atherosclerosis, diabetes mellitus, and arterial hypertension. Improved body composition, through exercise training and diet, may therefore significantly contribute to a reduction in oxidative stress. Further, some foods high in antioxidants (e.g., ginger) provide additional defense against oxidation. This study was conducted to assess the effects of ginger (***Zingiber officinale*** Roscoe) supplementation and progressive resistance training (PRT) on some nonenzymatic blood [total antioxidant capacity (TAC) and malondialdehyde (MDA)] oxidative stress markers in obese men. Thirty-two obese males (body mass index ≥30, aged 18-30 years) were randomized to one of the following four groups: a placebo (PL; n=8); resistance training plus placebo (RTPL; n=8); resistance training plus ginger supplementation (RTGI; n=8); and ginger supplementation only (GI; n=8). Participants in the RTGI and GI groups consumed 1g ginger/day for 10 weeks. At the same time, PRT was undertaken by the RTPL and RTGI groups three times/week. Resting blood samples were collected at baseline and at 10 weeks, and analyzed for plasma nonenzymatic TAC and MDA concentration. After the 10-week intervention, authors observed significant training×ginger supplementation×resistance training interaction for TAC (p=0.043) and significant interactions for training×resistance training and training×ginger supplementation for MDA levels (p<0.05). The results of this study show that 10 weeks of either ginger supplementation or PRT protects against oxidative stress and therefore both of these interventions can be beneficial for obese individuals; however, when combined, the effects cancel each other out.

17. Auddy, B., J. Hazra, A. Mitra, B. Abedon and S. Ghosal (2008). "**A standardized *Withania somnifera* extract significantly reduces stress-related parameters in chronically stressed humans: A double-blind, randomized, placebo-controlled study.**" The Journal of the American Nutraceutical Association **11**(1): 50-56.

Withania somnifera (WS) has historically been used in Asia for treating stress-related health conditions. In this study, authors investigated the effects of standardized WS root and leaf extract (WSE) in chronically stressed humans in a modern clinical trial. Participants were randomly assigned to WSE (125 mg QD, 125 mg BID, or 250 mg BID) or placebo groups. Stress levels were assessed at Days 0, 30, and 60 using a modified Hamilton anxiety (mHAM-A) scale. Biochemical and clinical variables were measured at Days 0 and 60. Of 130 subjects enrolled, 98 completed the study. Between Days 0 and 60, the WSE 125 mg QD group decreased significantly more than placebo for mean mHAM-A score, serum cortisol, serum C-reactive

protein, pulse rate and blood pressure, and increased significantly for mean serum DHEAS and hemoglobin. Other WSE treatment groups had greater dose-dependent responses in these parameters and had significantly greater responses compared to placebo in mean fasting blood glucose, serum lipid profiles and cardiac risk ratios. Participants and dropouts reported no adverse effects. Therefore, this study provides evidence that the consumption of WSE significantly reduces experiential and biochemical indicators of stress without adverse effects.

18. Awasthi, H., R. Nath, K. Usman, D. Mani, S. Khattri, A. Nischal, M. Singh and K. K. Sawlani (2015). "**Effects of a standardized Ayurvedic formulation on diabetes control in newly diagnosed Type-2 diabetics; a randomized active controlled clinical study.**" Complementary Therapies in Medicine **23**(4): 555-561.

The purpose of this study was to investigate the efficacy of a standardized polyherbal formulation consists of aqueous extracts from six herbs, in patients with Type-2 diabetes mellitus. Randomized, active control study. Interventions 93 patients, newly diagnosed with Type-2 diabetes mellitus were randomly allocated to group 1 (received polyherbal capsules containing six herbal extracts viz. *Berberis aristata, Cyperus rotundus, Cedrus deodara,* ***Emblica officinalis****,* ***Terminalia chebula*** and ***Terminalia bellirica***, 500 mg/day, up titrated weekly to a maximum of 3 g/day) and group 2 (received Metformin 500 mg/day, up titrated weekly to a maximum of 2 g/day). Main outcome measures were: the primary endpoint was effect on the change from baseline in blood glucose (Fasting blood Glucose and Postprandial blood glucose), and glycosylated hemoglobin (HbA1c). The secondary outcome includes the effect on lipid levels, liver enzymes and renal function test. After 24 weeks, mean laboratory measured fasting and post prandial blood glucose showed a decrease of 25.52% and 24.22% in polyherbal formulation (PHF) treated group, compared to 31.46% and 24% decrease in Metformin treated group (estimated treatment difference −10.8; 95% CI −22.63 to 1.03 and −0.36; −12.1 to 11.38, respectively). Reduction in HbA1c was also similar for PHF and Metformin (estimated treatment difference 0.01; 95% CI −0.51 to 0.53). However, **the decrease in the mean total cholesterol level was more pronounced in PHF treated group (estimated mean difference 61.3; 95% CI 55.32 to 67.28) than Metformin treated group (estimated mean difference 41.12; 95% CI 34.92 to 47.32).** Also, there was statistical significance between the treatment groups in total cholesterol level at the end of six months treatment (estimated treatment difference 20.18; 95% CI 12.34 to 28.02). The study demonstrated that daily intake of this PHF decreased the glycemic level and improved lipid homeostasis, while maintaining the other serum biochemical levels to the normal, and therefore it may be useful for the patients with Type-2 diabetes. This trial is registered in the Clinical Trials Registry – India (CTRI) (CTRI/2014/03/004490).

19. Ayaz, A. and V. D. Roshan (2012). "**Effects of 6-weeks water-based intermittent exercise with and without *Zingiber officinale* on pro-inflammatory markers and blood lipids in overweight women with breast cancer.**" Journal of Applied Pharmaceutical Science **2**(5): 218-224.

Overweight and obesity is a risk factor for breast cancer. In contrast, physical regular activity has been suggested to help increase the survival of individuals with breast

cancer. However, few studies have assessed effect of individually and combined ***Zingiber officinale*** (as a anti-inflammatory factor) with water-based exercise on the pro-inflammatory markers and blood lipid levels in overweight women with breast cancer and results have been inconsistent. The aim of this study was to determine the individual and concomitant effect of 6-wks water-based exercise and oral *Zingiber officinale* supplement on the aforesaid markers in overweight women with breast cancer. Forty women diagnosed with breast cancer(48±5.4 years, 76±9 kg, fat mass 41.8±4 %), volunteered to participate in the study. Subjects were randomly assigned into four groups; placebo, water-based exercise, *Zingiber officinale* and water-based exercise + *Zingiber officinale* groups. Subjects in the *Zingiber officinale* group and the exercise training+ *Zingiber officinale* group orally received 4 capsules (each capsule contained 750 mg), 7 days a week and for 6 weeks. The water-based exercise program were collected at a progressive intensity and time, ranged from 50% to 75% of heart rate reserve, in a pool with 15 meters width, 4 times a week for 6 weeks. Fasting blood sampling was collected at the pretest and post-test. The *Zingiber officinale* supplementation and or the water-base exercise resulted in a reduction of hs-CRP, IL-6 and TG, as compared to pretest. However, the combined intervention (water-base exercise and *Zingiber officinale*) group showed significantly a far better effect on the markers of pro-inflammatory and blood lipids, as compared to the water-base exercise or *Zingiber officinale* supplement alone groups and the age-matched placebo group. These findings indicate a protective effect of the nondrug strategies such as water-base exercise and anti-inflammatory herbal factors such as *Zingiber officinale* in the pathogenesis of inflammatory and metabolic responses in overweight women diagnosed with breast cancer.

20. Badar, V. A., V. R. Thawani, P. T. Wakode, M. P. Shrivastava, K. J. Gharpure, L. L. Hingorani and R. M. Khiyani (2005). "**Efficacy of *Tinospora cordifolia* in allergic rhinitis.**" Journal of Ethnopharmacology **96**(3): 445-449.

The efficacy of ***Tinospora cordifolia*** (TC) extract in patients of allergic rhinitis was assessed in a randomized double blind placebo controlled trial. Seventy-five patients were randomly given either TC or placebo for 8 weeks. They were clinically examined and Hb %, TLC, DLC and nasal smear was done. At the end of trial baseline investigations were repeated, drug decoded and results analyzed. With TC treatment 100% relief was reported from sneezing in 83% patients, in 69% from nasal discharge, in 61% from nasal obstruction and in 71% from nasal pruritus. In placebo group, there was no relief in 79% from sneezing, in 84.8% from nasal discharge, in 83% from nasal obstruction, and in 88% from nasal pruritus. The difference between TC and placebo groups was highly significant. TLC increased in 69% patients in drug treated group and in only 11% with placebo. After TC, eosinophil and neutrophil count decreased and goblet cells were absent in nasal smear. In the placebo group, decrease in eosinophil and neutrophil count was marginal and goblet cells were present. TC significantly decreased all symptoms of allergic rhinitis. Nasal smear cytology and leukocyte count correlated with clinical findings. TC was well tolerated.

21. Bajaj, N. and S. Tandon (2011). "**The effect of *Triphala* and Chlorhexidine mouthwash on dental plaque, gingival inflammation, and microbial growth.**" International Journal of Ayurveda Research **2**(1): 29-36.

The objective of this study was to ascertain the effects of a mouthwash prepared with ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) on dental plaque, gingival inflammation, and microbial growth and compare it with commercially available Chlorhexidine mouthwash. This study was conducted after ethics committee approval and written consent from guardians (and assent from the children) were obtained. A total of 1431 students in the age group 8-12 years, belonging to classes fourth to seventh, were the subjects for this study. The Knowledge, Attitude and Practice (KAP) of the subjects was determined using a questionnaire. The students were divided into three groups namely, Group I (n = 457) using *Triphala* mouthwash (0.6%), Group II (n = 440) using Chlorhexidine mouthwash (0.1%) (positive control), and Group III (n = 412) using distilled water (negative control). The assessment was carried out on the basis of plaque scores, gingival scores, and the microbiological analysis (Streptococcus and lactobacilli counts). Statistical analysis for plaque and gingival scores was conducted using the paired sample t-test (for intragroup) and the Tukey's test (for intergroup conducted along with analysis of variance test). For the Streptococcus mutans and Lactobacillus counts, Wilcoxon and Mann-Whitney test were applied for intragroup and intergroup comparison, respectively. All the tests were carried out using the SPSS software. Both the Group I and Group II showed progressive decrease in plaque scores from baseline to the end of 9 months; however, for Group III increase in plaque scores from the baseline to the end of 9 months was noted. Both Group I and Group II showed similar effect on gingival health. There was inhibitory effect on microbial counts except Lactobacillus where *Triphala* had shown better results than Chlorhexidine. It was concluded that there was no significant difference between the *Triphala* and the Chlorhexidine mouthwash.

22. Bandari, S. and P. Murthy (2012). "**Clinical Evaluation of Panchavaktra Ras in the Management of Amavata (Rheumatoid Arthritis).**" International Journal of Ayurvedic Medicine **3**(1): 22-39.

This study was conducted to evaluate the effectiveness of Panchavaktra Ras in the Management of Amavata (Rheumatoid Arthritis). A single blind clinical trial was conducted at Dr. Achanta Lakshmipati Govt. Ayurvedic Hospital, M.G. Road, Vijayawada. 50 patients were selected and trial drug was advocated in a dose of 300 mg. (2 tablets) twice a day with ***Trikatu*** (***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***) and Arka moola twak kashaya as anupana. Treatment was given for 45 days with the result assessment recorded at every 15 days. Subjective and objective parameters were analyzed before and after the treatment. In subjective parameters Sandhi Shula, Jadya, Angamarda, Alasya, Agnimandhya and Vidvibandha are taken, while Sandhi Shotha, Erythrocyte Sedimentation Rate (ESR) and R.A. Factor are considered as objective parameters. It was observed that 48% were in mild relief group, while 50% were of moderate relief and there was Good relief in 2% of patients. Both Subjective and Objective parameters have been analyzed statistically. The relief of Sandhi Shula, Stabdata, Angimandya, Angamarda, Alasya and Vidvibandha found highly significant ($P < 0.001$) and same results in reduction Sandhi Shotha, ESR levels and RA Factor. Panchavaktra Ras prepared as per the textual standards is highly effective in Amavata and showing a way out to the individual suffering from this

chronic disease. The study confirmed the effect of trial drug in Amavata (Rheumatoid arthritis) in improving the quality of life of patients without any untoward effects.

23. Banerjee, P., S. Maity, T. Das and S. Mazumder (2011). "**A double-blind randomized placebo-controlled clinical study to evaluate the efficacy and safety of a polyherbal formulation in geriatric age group: A phase IV clinical report.**" Journal of Ethnopharmacology **134**(2): 429-433.

Authors sought to determine the efficacy as antioxidant and safety profile of the polyherbal formulation in geriatric patients of eastern India. The study was double-blind, randomized including placebo controlled and was approved by the ethical committee of SSKM hospital. Geriatric patients attending the OPD (outpatient department) of SSKM hospital formed the study group. The patients were randomized to receive either the polyherbal formulation or the identical-looking placebo at a dose of 2 tablets twice daily for a period of 6 months. Each tablet of polyherbal formulation contained *Capparis spinosa* 13.8 mg, *Terminalia arjuna* 6.4 mg, ***Withania somnifera*** 30mg, *Asparagus racemosus* 20mg, *Glycyrrhiza glabra* 20 mg, *Centella asiatica* 20mg, ***Terminalia chebula*** 15mg and *Curcuma longa* 5 mg. Follow-up of patient status was done monthly. The clinical parameters were assessed before and after 6 months of medication or placebo intake. The results showed that significant rejuvenation of the anti-oxidant property which is determined by the enzymatic and non enzymatic anti oxidants, superoxide dismutase, catalase, glutathione peroxidase, glutathione reductase, reduced glutathione and malondialdehyde in the geriatric patients were seen in patients treated with Geriforte tablets as compared to patients treated with placebo and control group. There were no significant adverse effects experienced by cases in any group. Polyherbal formulation is effective in rejuvenating geriatric age group compared to the placebo. This formulation is safe and compliance to the treatment was good. In ancient Ayurveda the constituents of polyherbal formulation were prescribed for different diseases including cardiological, neurological, sepsis, etc.

24. Bansal, P., R. Sannd, N. Srikanth and G. Lavekar (2009). "**Effect of traditionally designed nutraceutical on stress induced immunoglobulin changes at Antarctica.**" African Journal of Biochemistry Research **3**(4): 84-88.

This study was conducted to establish the effect of a traditionally designed nutraceutical on stress related changes in selected immunoglobulin levels in the body. The nutraceutical containing Ashwagandha (***Withania somnifera***), Guduchi (***Tinospora cordifolia***), Safed musli (*Chlorophytum arundinaceum*), Pippali (***Piper longum***), Badam (*Prunus amygdalus*) and some other herbs was prepared from different potent herbs described in Ayurveda using standard operative procedures and were tested for heavy metal and microbial load. Initially, 21 subjects were selected in addition to 7 volunteers for control group who did not consume nutraceutical. Sampling was done at zero days and at fortnightly intervals. The levels of selected immunoglobulin IgG, IgA and IgM were estimated with turbidity metric immunoassay at different time intervals. The concentration of immunoglobulin IgA was 146±15.96 at zero day stage. The levels of these immunoglobulins were lower at all stages as compared to the concentration at zero day in trial group subjects whereas the concentration was significantly higher (t stat.>t critic. at $p<0.05$) in

control group subjects. The concentration of IgG was very high to the tune of 3091±705 at zero day stage. The level of IgG was lower in trial subjects as compared to control subjects at all stages except at the 6th week stage where it was higher in trial subjects. Concentration of immunoglobulin IgM was 80.75±30.39 (t stat.>t critic. at $p<0.05$) at zero day followed by a decrease in both groups at the 2nd week, however **the concentration was almost 1/3 rd in trial drug subjects as compared to the levels in control subjects followed by an abrupt increase at the 4th week**. The levels increased to 106±8.94 at the 4th week stage and 115±9.35 at the 6th week stage in control subjects (even higher than at zero day) whereas the values were 46.15±11.39 and 55.38±15.34 (t stat.>t critic. at $p<0.05$) at respective stages in trial drug subjects. On the whole the pattern of fall and rise in levels of IgM were similar in the control as well as treatment group subjects at all stages. Studies revealed that the components of the nutraceutical tended to exert significant (t stat.>t critic. at $p<0.05$) anti-stress effect against stress related changes in immunoglobulin in the body due to the battery of stresses encountered at Antarctica.

25. Bargale, S. S., H. Shashirekha and U. C. Baragi (2014). "**Anti-aging effect of amalaki rasayana in healthy elderly subjects.**" Journal of Ayurveda and Holistic Medicine (JAHM) **2**(1): 10-18.

Aging is the accumulation of changes in a person over time. Ageing in humans refers to a multidimensional process of physical, psychological, and social change. The increasing number of the aged (≥60 years) in the present scenario signifies a new outlook for our reflection. Populations worldwide are ageing. In present era, medical science deals exclusively with the problem of ageing and the diseases of the elderly. Ayurveda is basically the science of life and longevity. It presents a good concept of ageing, process of delaying the ageing and its management. Amalaki Rasayana (with ***Emblica officinalis***) consist of rich of vitamin C, both ascorbic acid and its oxidized product dehydroascrobic acid are biological active, active vitamin C enhances promotion of non heam absorption. Aims and objectives were to evaluate the effect of amalaki rasayana in healthy elderly person. The clinical study was carried out to evaluate the efficacy of amalaki rasayana in subjects above 60 yr to 75 yrs. These subjects were divided in to two group A and B in 15 each. Person were given placebo capsule 60 days in group A and amalaki rasayana in the dose 10 gm once in a day for 60 days in group B and effect was evaluated on pre-test and post-test design. **Statistically significant ($p<0.01$) results were seen in subjective symptoms like physical disability, insomnia, difficulty in breathing, grasping power, loss of appetite, constipation, flabbiness of joint** etc. The trial drug amalaki rasayana along with milk has shown highly significant result in treating symptoms like insomnia, constipation, digestive weakness and hemoglobin percentage. Hence amalaki rasayana along with milk is very effective in treating ageing ailments.

26. Betz, O., P. Kranke, G. Geldner, H. Wulf and L. H. J. Eberhart (2005). "**Is ginger a clinically relevant antiemetic? A systematic review of randomized controlled trials.**" Forschende Komplementarmedizin und Klassische Naturheilkunde **12**(1): 14-23.

The aim of this systematic review was to evaluate the clinical impact of ginger (***Zingiber officinale***) as an antiemetic. A systematic search of the literature was performed using the databases of MEDLINE, EMBASE, and the Cochrane-Library. Of

100 published reports discerned as potentially relevant, 24 randomized controlled trials were evaluated, covering 1073 patients which had received ginger. Of these reports, 16 contained information regarding the antiemetic activity of the phytotherapeutic agent against kinetosis, postoperative nausea and vomiting (PONV), and morning sickness and hyperemesis gravidarum, respectively. Only a few studies were eligible for a quantitative analysis (meta-analysis). Thus, the majority of the reports were analyzed descriptively. To analyze the potential side effects of the drug, 15 reports with 777 patients were eligible. Of these, 3.3% suffered from slight side effects, mainly mild gastrointestinal symptoms and sleepiness, both not requiring specific treatments. One severe adverse event was reported in a study: an abortion occurred in the 12th week of gestation. However, a total of 136 patients were treated with ginger within the first trimenon of pregnancy without complications. There is no clear evidence for the efficacy of ginger in the treatment of PONV and of kinetosis. The results for the treatment of nausea and vomiting in pregnancy are encouraging, however, ginger should be applied for the time being only in controlled clinical studies. Applied in daily doses up to 6 g ginger seems to be a drug with few side effects.

27. Bhattacharjee, R., S. Nekkanti, N. G. Kumar, K. Kapuria, S. Acharya and K. C. Pentapati (2015). "**Efficacy of *Triphala* mouth rinse (aqueous extracts) on dental plaque and gingivitis in children.**" Journal of Investigative and Clinical Dentistry **6**(3): 206-210.

The aim of the present study was to evaluate the efficacy of ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) mouth rinse (aqueous) in the reduction of plaque and gingivitis among children. The study was a randomized, double-blinded, controlled trial, with a total of 60 school children (n = 30 in each group; *Triphala* and chlorhexidine groups). Plaque and gingival indices were used to evaluate baseline and follow-up plaque and gingivitis. A total of 57 children completed the study. Both chlorhexidine and *Triphala* groups showed significantly lower mean gingival and plaque index scores at follow up than baseline ($P < 0.001$). There was no significant difference in the percentage change in the mean gingival index between the two groups ($P = 0.826$). The percentage change in the mean plaque index was significantly higher in the chlorhexidine group compared to the *Triphala* group ($P = 0.048$). The effectiveness of *Triphala* in the reduction of plaque and gingivitis was comparable to chlorhexidine, and can be used for short-term purposes without potential side-effects. It is a cost-effective alternative in reducing plaque and gingivitis.

28. Bhosale, S. and S. Kapgate (2015). "**Effect of Hingu-Pippali Yoga, a herbal formulation in respiratory disorders caused by air pollution in traffic police - A pilot study.**" Asian Journal of Water, Environment and Pollution **12**(2): 99-106.

Traffic police in metropolitan cities are exposed to higher level of air pollution and are suffering from respiratory symptoms. Conventional symptomatic treatment is effective to give temporary relief but the lung capacity of the subjects reduces progressively. Present study was aimed to evaluate effect of Hingu-Pippali yoga, a herbal formulation in containing ***Piper longum***, respiratory disorders caused due to air pollution in traffic police. With a prior institutional ethical permission an open, randomised clinical study was carried out. Informed consent was taken from every

subject enrolled in trial. An authenticated and standardised test drug was administered twice a day in dose of 250 mg for 28 days with honey and sugar to trial group. Lung function test with spirometer and Haemogram before starting the treatment and at the end of study was done to evaluate the results. The subjective parameters viz. cough, rhinitis and dyspnoea showed significant reduction ($p < 0.001$) in trial group. Pulmonary Function Tests-FVC, FEV1, MVV and FEF ($p < 0.001$)-showed significant results indicating the increase in lung capacity in trial group. There was significant reduction seen in eosinophil count and ESR. Hingu-pippali yoga is effective to reduce the respiratory disorders caused due to air pollution and enhances the lung capacity of subjects.

29. Bhuyan, C., S. Gupta and T. Dudhamal (2015). "**Clinical effect of Madhu Amalaki Rasayan (MAR) in the treatment of Amlapitta. WSR to acid peptic disorders.**" Indian Journal of Ancient Medicine & Yoga **8**(3): 129-134.

Amlapitta is a very common disease which can be correlated with Acid peptic disorder (APD) in modern parlance. In Ayurveda the main cause of Amlapitta is due to Agnimandya (Indigestion), different dietetic habits like Adhyashan (Intake of food before digestion), Vishmashana (Irregular food intake) and spiced oily food etc. and the psychic factors like Chinta (anxiety) Udveg (Stress), Krodha (Anger) etc. In modern the causative factors are mainly hurry, worry and curry adding new sherry (Alcohol) and mechanical lifestyle with unsuitable food habits. The disease became chronic due to negligence and western life style adopting in diet and routine activity which is nonconductive regimen in our Indian climate. In this study 80 patients of Amlapitta were selected and divided into two groups. In group-A (Treated group) 50 patients were treated with Ayurveda formulation tablet Madhu Amalaki Rasayan (MAR) containing ***Emblica officinalis***, 250 mg two times a day before meal. In group-B (Control group) 30 patients were treated with modern medicine i.e. tablet famotidine-20 mg two times a day before meal. The treatment was continued for consecutive 30 days in both groups and patients were followed up for further two months by every fortnight. Lastly study concluded that tablet Madhu Amalaki Rasayan (MAR) is better as a remedial measure for Amlapitta having good palatability without any adverse effect.

30. Binorkar, S. V., C. M. Sreekrishnan and K. V. Asha (2013). "**Role of bilwadi agada in the management of scorpion sting.**" International Journal of Research in Ayurveda and Pharmacy **4**(1): 59-62.

Scorpion sting is a particularly devastating and an endemic public health problem in some part of the India. 50 species out of 700 in India can cause serious illness. Most of the studies have focused on the clinical and epidemiological aspects of scorpion stings. Ayurveda has explained numerous medicinal preparations for the management of Vrishchika Damsha (Scorpion sting) but so far very little statistical data is available regarding the efficacy of these medicines particularly in the management of pain. This Paper is focused on efficacy of one of such preparations, Bilwadi Agada which was a part of research for internal medications. A clinical study was conducted in 2005 at Pappinissery Visha Chikitsa Kendra, Kannur. Total 10 subjects suffering from Scorpion sting satisfying inclusion criteria were selected and after obtaining consent, treated with Bilwadi Agada for 4 days. Drug contains *Aegle*

marmelos, Berberis aristata, ***Piper nigrum****,* ***Piper longum****, Cedrus deodara, Curcuma longa,* ***Emblica officinalis****, Ocimum tenuiflorum, Pongamia pinnata,* ***Terminalia bellirica****,* ***Terminalia chebula****,* and *Valeriana wallichii*. Thorough clinical assessment was done before and after the treatment. The result was analyzed statistically with paired t-test which was found highly significant in reducing the cardinal symptom, pain, erythema and inflammation in scorpion sting (P<0.001). Drug also proved effective in reducing other associated symptoms like burning sensation and itching sensations in Scorpion sting.

31. Bisht, D., Y. Sharma and B. Mehra (2009). "**A clinical study to evaluate the efficacy of Pippali Rasayana in certain respiratory disorders.**" AYU **30**(3): 337-341.

Two million people die per year due to pulmonary tuberculosis all over the world. The 15 million new cases are diagnosed every year in India, of which 90% have pulmonary tuberculosis. Chronic bronchitis is the second most common lung disorder after pulmonary tuberculosis equally prevalent in rural and urban areas. Similarly nearly 6% population suffers from Bronchial asthma in India. Respiratory system is one such in human body which gets affected from a variety of infections and condition may become worse when body lacks sufficient immunity. Though drugs like corticosteroids, bronchodilators, anti tubercular therapy offer relief but may have many side effects. In Ayurveda answer to these problems is Rasayana therapy. Role of Rasayana therapy with recent advancement can be adjusted in terms of immuno modulatory, cytoprotective, genoprotective, adaptogenic, stress reliever actions etc. In this study a textual formulation. 'Pippali Rasayana' was given for a period of 45 days after Koshtha shodhana to 15 patients diagnosed with common respiratory diseases. Pippali Rasayana (PR) is an Ayurvedic drug prepared from Palash (*Butea monosperma* (Lamk) Kuntze; Leguminaceae) and Pippali (***Piper longum*** L.; Piperaceae). Control group of 12 patients was observed as such while taking their respective medications. A remarkable improvement was noted in clinical features as well as general conditions of these patients indicating the beneficial role of 'Pippali Rasayana' as adjuvant.

32. Biswal, B. M., S. A. Sulaiman, H. C. Ismail, H. Zakaria and K. I. Musa (2013). "**Effect of *Withania somnifera* (Ashwagandha) on the development of chemotherapy-induced fatigue and quality of life in breast cancer patients.**" Integrative Cancer Therapies **12**(4): 312-322.

Hypothesis was that ***Withania somnifera*** is an herb with antioxidant, anti-inflammatory, anticancer, antistress, and adaptogenic properties. Previous studies have shown its antistress effects in animals. Traditional Indian medicine has used it for centuries to alleviate fatigue and improve general well-being. This is an open-label prospective nonrandomized comparative trial on 100 patients with breast cancer in all stages undergoing either a combination of chemotherapy with oral ***Withania somnifera*** or chemotherapy alone. The chemotherapy regimens were either taxotere, adriamycin, and cyclophosphamide or 5-fluorouracil, epirubicin, and cyclophosphamide. *Withania somnifera* root extract was administered to patients in the study group at a dose of 2 g every 8 hours, throughout the course of chemotherapy. The quality-of-life and fatigue scores were evaluated before, during, and on the last cycles of chemotherapy using the EORTC QLQ-C30 (Version 3), Piper

Fatigue Scale (PFS), and Schwartz Cancer Fatigue Scale (SCFS-6). Results. The median age distributions in the study and control arm were 51 years (range = 36-70) and 50.5 years (range = 32-71), respectively. The majority (77%) of patients had stage II and III disease. Patients in the control arm experienced statistically significant higher estimated marginal means of fatigue score compared with the study group (P <.001 PFS, P <.003 SCFS-6). Furthermore, various symptom scales of the EORTC QLQ-C30 were statistically significant in 7 out of 18 symptoms in the intervention group compared with the control group (P <.001). The 24-month overall survival for all stages in study and control group patients were 72% versus 56%, respectively; however, the result was not significant (P =.176), at a median follow-up duration of 26 months. *Withania somnifera* has potential against cancer-related fatigue, in addition to improving the quality of life. However, further study with a larger sample size in a randomized trial is warranted to further validate these findings.

33. Biswas, N. R., S. K. Gupta, G. K. Das, N. Kumar, P. K. Mongre, D. Haldar and S. Beri (2001). "**Evaluation of Ophthacare® eye drops - A herbal formulation in the management of various ophthalmic disorders.**" Phytotherapy Research **15**(7): 618-620.

An open prospective multicentre clinical trial was conducted in patients suffering from various ophthalmic disorders namely, conjunctivitis, conjunctival xerosis (dry eye), acute dacryocystitis, degenerative conditions (pterygium or pinguecula) and postoperative cataract patients with a herbal eye drop preparation (Ophthacare®) containing basic principles of different herbs which have been conventionally used in the Ayurvedic system of medicine since time immemorial. These include *Carum copticum*, ***Terminalia bellirica***, ***Emblica officinalis***, *Curcuma longa*, *Ocimum sanctum*, *Cinnamomum camphora*, *Rosa damascena* and meldespumapum. These herbs reportedly posses antiinfective and antiinflammatory properties. The present study was undertaken to elucidate the role of this herbal product in a variety of eye ailments. Side effects, if any, were noted during the study. An improvement was observed with the treatment of the herbal eye drop treatment in most cases. There were no side effects observed during the course of the study and the eye drop was well tolerated by the patients. The herbal eye drop Ophthacare® has a useful role in a variety of infective, inflammatory and degenerative ophthalmic disorders.

34. Biswas, P., A. Saha and L. N. Maity (2015). "**Antistress activity of *Tinospora cordifolia* with application of Yoga.**" International Journal of Ayurvedic Medicine **6**(3): 220-224.

Mental stress can lead to various biochemicals, physiological and psychological changes in human body. The present study was designed to evaluate the antistress activities of ***Tinospora cordifolia*** (wild) Miers associated with yoga. Methods: A randomized double blind placebo control 8 weeks study was conducted. The mental stress patients were diagnosed clinically by using different validated psychological rating scales. A total of 63 patients with mental stress were randomized into four groups. The antistress activities of the treatments were measured by different psychological rating scales as well as various biochemical parameters i.e. lipid profile, serum glucose concentration. The serum glucose, lipid like triglyceride, cholesterol, ldl –cholesterol and psychological parameters like anxiety, depression were significantly increases in patients with chronic mental stress. However following treatment with *Tinospora cordifolia* associated with practice of yoga significantly

reduced various stress induced psychological and biochemical parameters (P< 0.001). The findings of the clinical study suggested that *Tinospora cordifolia* and practice of yoga have significant anti stress activities as shown by its mitigating effects on chronic stress induced psychological and biochemical perturbation comparable to that induced by well known adaptogenic agent diazepam.

35. Biswas, S. C., R. Dey, G. S. Kamliya, R. Bal, A. Hazra and S. K. Tripathi (2011). "**A single-masked, randomized, controlled trial of ginger extract in the treatment of nausea and vomiting of pregnancy.**" Journal International Medical Sciences Academy **24**(4): 167-169.

In order to evaluate the efficacy and tolerability of an oral ginger (***Zingiber officinale***) extract formulation in comparison to oral fixed dose combination of doxylamine 10 mg plus pyridoxine 10 mg, seventy eight (78) women between 6-16 weeks of pregnancy, complaining of nausea and vomiting (NVP), were randomized to receive either ginger formulation or pyridoxine-doxylamine preparation in a single blind fashion. Efficacy variables were the severity of nausea and vomiting scored by visual analog scale, on the day of each visit, as well as averaged over the past week; the average number of nausea spells or vomiting episodes per day over the past week; and subjective well-being assessed as a binary variable. Study was completed by 63 women (34 on ginger extract). Statistically, no appreciable difference in efficacy parameters was noted between groups. Tolerability of ginger extract was satisfactory with no severe or serious adverse events noted. Ginger extract can provide a safe and effective alternative for management of NVP.

36. Biswas, T. K., S. Chakrabarti, S. Pandit, U. Jana and S. K. Dey (2014). "**Pilot study evaluating the use of *Emblica officinalis* standardized fruit extract in cardio-respiratory improvement and antioxidant status of volunteers with smoking history.**" Journal of Herbal Medicine **4**(4): 188-194.

Emblica officinalis (Indian Goosebery, ***Phyllanthus emblica***) was evaluated for cardio-respiratory and anti-oxidant status in human volunteers with a long smoking history, using a randomized, double-blind, placebo controlled pilot study. *Emblica officinalis* fruit extract (EOE) standardized to contain not less than 60% (w/w) of low molecular weight hydrolyzable tannoids (Emblicanin-A, Emblicanin-B, Pedunculagin, Punigluconin) was used in this randomized, double-blind, placebo-controlled clinical study, with Group I consisting of 20 subjects receiving 250 mg of EOE twice a day for 60 days and Group II consisting of 10 subjects receiving 250 mg of placebo twice a day for 60 days. Subjective parameters - mouth hygiene, cough with expectoration, shortness of breath on exertion, loss of appetite, feelings of impending doom, palpitation, sleep deprivation, irritability, heart burn and tiredness were evaluated at 0 (baseline), 30 and 60 days. Objective parameters - hemogram, lipid profile, cardiovascular risk factors, genotoxicity, antioxidant status and pulmonary function were assessed at days 0 (baseline) and 60 of the study. EOE treated group showed a significant improvement compared to the placebo group in all the subjective and objective parameters tested with no reports of adverse events. This pilot study provides some further evidence of the protective effect of *Emblica officinalis* in cardio-respiratory and antioxidant status of volunteers with chronic smoking history.

37. Black, C. D., M. P. Herring, D. J. Hurley and P. J. O'Connor (2010). "**Ginger (*Zingiber officinale*) reduces muscle pain caused by eccentric exercise.**" Journal of Pain **11**(9): 894-903.

Ginger (***Zingiber officinale***) has been shown to exert anti-inflammatory effects in rodents, but its effect on human muscle pain is uncertain. Heat treatment of ginger has been suggested to enhance its hypoalgesic effects. The purpose of this study was to examine the effects of 11 days of raw (study 1) and heat-treated (study 2) ginger supplementation on muscle pain. Study 1 and 2 were identical double-blind, placebo controlled, randomized experiments with 34 and 40 volunteers, respectively. Participants consumed 2 grams of either raw (study 1) or heated (study 2) ginger or placebo for 11 consecutive days. Participants performed 18 eccentric actions of the elbow flexors to induce pain and inflammation. Pain intensity, perceived effort, plasma prostaglandin E 2, arm volume, range-of-motion and isometric strength were assessed prior to and for 3 days after exercise. Results Raw (25%, -.78 SD, P = .041) and heat-treated (23%, -.57 SD, P = .049) ginger resulted in similar pain reductions 24 hours after eccentric exercise compared to placebo. Smaller effects were noted between both types of ginger and placebo on other measures. Daily supplementation with ginger reduced muscle pain caused by eccentric exercise, and this effect was not enhanced by heat treating the ginger. This study demonstrates that daily consumption of raw and heat-treated ginger resulted in moderate-to-large reductions in muscle pain following exercise-induced muscle injury. These findings agree with those showing hypoalgesic effects of ginger (*Zingiber officinale*) in osteoarthritis patients and further demonstrate ginger's effectiveness as a pain reliever.

38. Bone, M. E., D. J. Wilkinson, J. R. Young, J. McNeil and S. Carlton (1990). "**Ginger root - a new antiemetic. The effect of ginger root on postoperative nausea and vomiting after major gynaecological surgery.**" Anaesthesia **45**(8): 669-671.

The effectiveness of ginger (***Zingiber officinale***) as an antiemetic agent was compared with placebo and metoclopramide in 60 women who had major gynaecological surgery in a double-blind, randomized study. There were statistically significantly fewer recorded incidences of nausea in the group that received ginger root compared with placebo ($p < 0.05$). The number of incidences of nausea in the groups that received either ginger root or metoclopramide were similar. The administration of antiemetic after operation was significantly greater in the placebo group compared to the other two groups ($p < 0.05$).

39. Borrelli, F., R. Capasso, G. Aviello, M. H. Pittler and A. A. Izzo (2005). "**Effectiveness and safety of ginger in the treatment of pregnancy-induced nausea and vomiting.**" Obstetrics and Gynecology **105**(4): 849-856.

Conventional antiemetics are burdened with the potential of teratogenic effects during the critical embryogenic period of pregnancy. Thus, a safe and effective medication would be a welcome addition to the therapeutic repertoire. This systematic review was aimed at assessing the evidence for or against the efficacy and safety of ginger (***Zingiber officinale***) therapy for nausea and vomiting during pregnancy. Systematic literature searches were conducted in 3 computerized databases (MEDLBME, EMBASE, and Cochrane Library), and the reference lists of all

papers located were checked for further relevant publications. For the evaluation of efficacy, only double-blind, randomized controlled trials (RCTs) were included. All retrieved clinical data, including uncontrolled trials, case reports, observational studies, and RCTs, were included in the review of safety. Six double-blind RCTs with a total of 675 participants and a prospective observational cohort study (n = 187) met all inclusion criteria. The methodological quality of 4 of 5 RCTs was high. Four of the 6 RCTs (n = 246) showed superiority of ginger over placebo; the other 2 RCTs (n = 429) indicated that ginger was as effective as the reference drug (vitamin B6) in relieving the severity of nausea and vomiting episodes. The observational study retrieved and RCTs (including follow-up periods) showed the absence of significant side effects or adverse effects on pregnancy outcomes. There were no spontaneous or case reports of adverse events during ginger treatment in pregnancy. Ginger may be an effective treatment for nausea and vomiting in pregnancy. However, more observational studies, with a larger sample size, are needed to confirm the encouraging preliminary data on ginger safety.

40. Brockwell, C., S. Ampikaipakan, D. W. Sexton, D. Price, D. Freeman, M. Thomas, M. Ali and A. M. Wilson (2014). "**Adjunctive treatment with oral AKL1, a botanical nutraceutical, in chronic obstructive pulmonary disease.**" International Journal of COPD **9**: 715-721.

The objective of this pilot trial was to evaluate the safety and efficacy of AKL1, a patented botanical formulation containing extracts of *Picrorhiza kurroa*, *Ginkgo biloba*, and ***Zingiber officinale***, as add-on therapy for patients with chronic obstructive pulmonary disease (COPD) and chronic cough. Patients and methods: This randomized, double-blind, placebo-controlled trial enrolled male and female patients >18 years old with COPD and Leicester Cough Questionnaire (LCQ) score of <18. The 10-week study period comprised a 2-week single-blind placebo run-in period followed by add-on treatment with AKL1 or placebo twice daily for 8 weeks. The primary study endpoint was the change from week 0 to week 8 in cough-related health status, as assessed by the LCQ. Results: Of 33 patients enrolled, 20 were randomized to AKL1 and 13 to placebo. Patients included 19 (58%) men and 14 (42%) women of mean (standard deviation [SD]) age of 67 (9.4) years; 15 (45%) patients were smokers and 16 (49%) were ex-smokers. The mean (SD) change from baseline in LCQ score at 8 weeks was 2.3 (4.9) in the AKL1 group and 0.6 (3.7) in the placebo group, with mean difference in change of 1.8 (95% confidence interval: -1.5 to 5.1; P=0.28). The St George's Respiratory Questionnaire score improved substantially in the AKL1 treatment group by a mean (SD) of -7.7 (11.7) versus worsening in the placebo group (+1.5 [9.3]), with mean difference in change of -9.2 (95% confidence interval: -19.0 to 0.6; P=0.064). There were no significant differences between treatment groups in change from baseline to week 8 in other patient-reported measures, lung function, or the 6-minute walk distance. Further study is needed with a larger patient population and over a longer duration to better assess the effects of add-on therapy with AKL1 in COPD.

41. Cady, R. K., J. Goldstein, R. Nett, R. Mitchell, M. E. Beach and R. Browning (2011). "**A Double-Blind Placebo-Controlled Pilot Study of Sublingual Feverfew and Ginger (LipiGesicTMM) in the Treatment of Migraine.**" Headache: The Journal of Head and Face Pain **51**(7): 1078-1086.

Therapeutic needs of migraineurs vary considerably from patient to patient and even attack to attack. Some attacks require high-end therapy, while other attacks have treatment needs that are less immediate. While triptans are considered the "gold standard" of migraine therapy, they do have limitations and many patients are seeking other therapeutic alternatives. In 2005, an open-label study of feverfew/ginger suggested efficacy for attacks of migraine treated early during the mild headache phase of the attack. In this multi-center pilot study, 60 patients treated 221 attacks of migraine with sublingual feverfew/ginger or placebo. All subjects met International Headache Society criteria for migraine with or without aura, experiencing 2-6 attacks of migraine per month within the previous 3 months. Subjects had <15 headache days per month and were not experiencing medication overuse headache. Inclusion required that subjects were able to identify a period of mild headache in at least 75% of attacks. Subjects were required to be able to distinguish migraine from non-migraine headache. Subjects were randomized 3:1 to receive either sublingual feverfew/ginger or a matching placebo and were instructed but not required to treat with study medication at the earliest recognition of migraine. Sixty subjects treated 208 evaluable attacks of migraine over a 1-month period; 45 subjects treated 163 attacks with sublingual feverfew/ginger and 15 subjects treated 58 attacks with a sublingual placebo preparation. Evaluable diaries were completed for 151 attacks of migraine in the population using feverfew/ginger and 57 attacks for those attacks treated with placebo. At 2 hours, 32% of subjects receiving active medication and 16% of subjects receiving placebo were pain-free (P = .02). At 2 hours, 63% of subjects receiving feverfew/ginger found pain relief (pain-free or mild headache) vs 39% for placebo (P = .002). Pain level differences on a 4-point pain scale for those receiving feverfew/ginger vs placebo were −0.24 vs −0.04 respectively (P = .006). Feverfew/ginger was generally well tolerated with oral numbness and nausea being the most frequently occurring adverse event. Sublingual feverfew/ginger (***Zingiber officinale***) appears safe and effective as a first-line abortive treatment for a population of migraineurs who frequently experience mild headache prior to the onset of moderate to severe headache.

42. Carounanidy, U., R. Satyanarayanan and A. Velmurugan (2007). "**Use of an aqueous extract of *Terminalia chebula* as an anticaries agent: A clinical study.**" Indian Journal of Dental Research **18**(4): 152-156.

Plant-derived medicines have been a part of our traditional health care system, and the antimicrobial properties of plant-derived compounds are well documented. The purpose of this study is to evaluate the effect of an aqueous extract of ***Terminalia chebula*** (a medicinal plant) on salivary samples and its potential for use as an anticaries agent in the form of mouthwash. A concentrated aqueous extract was prepared from the fruit of T. chebula. A mouth rinse of 10% concentration was prepared by diluting the extract in sterile distilled water. The efficacy of the mouth rinse was assessed by testing on 50 salivary samples. Salivary samples were collected from subjects assessed to be at high risk for caries. Salivary pH, buffering capacity, and microbial activity were assessed before rinsing, immediately after, and 10 min, 30 min, and 1 h after rinsing. There was an increase in the pH and buffering capacity and decrease in microbial count. An aqueous extract of T. chebula used as a mouth rinse seems to be an effective anticaries agent.

43. Castillo, A., J. Ramos, J. De Francia, P. Quilala and M. Dujunco (2014). "**Immunomodulatory effects of *Tinospora cordifolia* lotion on interleukin-1, interleukin-6 and interleukin-8 levels in scabies-infected pediatric patients: a single blind, randomized trial.**" Intl J Pharma Sci Drug Res **6**: 204-210.

Scabies is a contagious, parasitic skin infestation caused by Sarcoptes scabiei mite, which has the ability to regulate the host's inflammatory and immune responses. It is a serious community health problem in many less-developed countries. A randomized, controlled, parallel, pilot clinical study was performed to investigate the immunomodulatory effect of the formulated Tinospora lotion in clinically diagnosed scabies-infected patients through Enzyme-Linked Immunosorbent Assay (ELISA) for Interleukin-1, Interleukin-6 and Interleukin-8 using blood serum samples. The pediatric patients were treated with ***Tinospora cordifolia*** and Permethrin lotions for three consecutive days for two weeks. Blood extraction was performed before and after the second and fourth week of treatment period. *Tinospora cordifolia* lotion significantly reduced the Interleukin-1 (IL-1) and Interleukin-6 (IL-6) levels from Day 14 to Day 28 ($p=0.0002$) comparable to Permethrin lotion ($p<0.050$). Permethrin efficiently decreased Interleukin-8 (IL-8) levels than Tinospora at Day 14 ($p=0.0155$). Down regulation of Interleukin 1, 6, and 8 levels in scabies infestation inhibits hyperkeratosis and infiltration of inflammatory cells into scabietic lesion. The modulation effect of the Tinospora lotion on interleukin levels reinforces its anti-scabies activity.

44. Castillo, A. L., M. O. Osi, J. D. A. Ramos, J. L. De Francia, M. U. Dujunco and P. F. Quilala (2013). "**Efficacy and safety of *Tinospora cordifolia* lotion in Sarcoptes scabiei var hominis-infected pediatric patients: A single blind, randomized controlled trial.**" Journal of Pharmacology and Pharmacotherapeutics **4**(1): 39-46.

Objective was to evaluate the clinical efficacy and safety of ***Tinospora cordifolia*** lotion including its cure rate and clearance time compared with permethrin lotion. Materials and Methods: A single blind, randomized, controlled, pilot clinical study was performed in three government institutions to investigate clinical efficacy of *T.cordifolia* lotion in sixty-six clinically-diagnosed scabies-infected patients. The patients were treated with *T.cordifolia* or permethrin lotions for three consecutive days for two weeks and clinical assessment of each patient was performed for five weeks. *T. cordifolia* lotion and permethrin significantly reduced the mean global evaluation score after four weeks of treatment. The two lotions showed comparable effects as anti-scabies agent. Moreover, the clearance time (days) and cure rate using the two lotions did not differ. Clinical improvement, mean clearance time and cure rate of *T. cordifolia* lotion are comparable with permethrin. *Tinospora cordifolia* lotion exhibits anti-scabies activity comparable with permethrin. Its incorporation as therapeutic reagent in Sarcoptes scabiei infections is highly recommended.

45. Chandrasekhar, K., J. Kapoor and S. Anishetty (2012). "**A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of Ashwagandha root in reducing stress and anxiety in adults.**" Indian Journal of Psychological Medicine **34**(3): 255-262.

Stress is a state of mental or emotional strain or tension, which can lead to underperformance and adverse clinical conditions. Adaptogens are herbs that help in combating stress. Ayurvedic classical texts, animal studies and clinical studies describe Ashwagandha (***Withania somnifera***) as a safe and effective adaptogen. The aim of the study was to evaluate the safety and efficacy of a high-concentration full-spectrum extract of Ashwagandha roots in reducing stress and anxiety and in improving the general well-being of adults who were under stress. It was a single center, prospective, double-blind, randomized, placebo-controlled trial. A total of 64 subjects with a history of chronic stress were enrolled into the study after performing relevant clinical examinations and laboratory tests. These included a measurement of serum cortisol, and assessing their scores on standard stress-assessment questionnaires. They were randomized to either the placebo control group or the study drug treatment group, and were asked to take one capsule twice a day for a period of 60 days. In the study drug treatment group, each capsule contained 300 mg of high-concentration full-spectrum extract from the root of the Ashwagandha plant. During the treatment period (on Day 15, Day 30 and Day 45), a follow-up telephone call was made to all subjects to check for treatment compliance and to note any adverse reactions. Final safety and efficacy assessments were done on Day 60. Statistical Analysis: t-test, Mann-Whitney test. The treatment group that was given the high-concentration full-spectrum Ashwagandha root extract exhibited a significant reduction ($P<0.0001$) in scores on all the stress-assessment scales on Day 60, relative to the placebo group. The serum cortisol levels were substantially reduced ($P=0.0006$) in the Ashwagandha group, relative to the placebo group. The adverse effects were mild in nature and were comparable in both the groups. No serious adverse events were reported. The findings of this study suggest that a high-concentration full-spectrum Ashwagandha root extract safely and effectively improves an individual's resistance towards stress and thereby improves self-assessed quality of life.

46. Chaudhary, S. A., K. Patel, V. Kori and S. Rajagopala (2012). "**Management of doshika kasa in sub-acute and chronic stage with vyaghri haritaki avaleha in children.**" Trials **21**: 09.

Respiratory Tract Infections (RTI) accounting about more than 50% of patients attending pediatric OPD as cough is the most frequent symptom of respiratory diseases majority of the patients' present recurrent cough as the manifestation of recurrent respiratory disease. From the Ayurvedic point of view, the descriptions about the disease Kasa clearly correlates with cough. Moreover the pathophysiology of Kasa almost exactly correlates the mechanism of cough reflex. It is important to treat any disease in childhood age at the earliest as it may hamper the Growth and development of child. Long standing disease affects the immunity and chronicity of the Kasa leads to Kshaya which has multi-system involvement. Due to disease, school absenteeism and expenditures of medicine are the burden on the society. As Kasa is Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, clinical study was undertaken on Kasa in sub-acute and chronic stage for duration of 4 weeks and also with follow-up of 4 weeks. The drug Vyaghri Haritaki Avaleha was given orally with luke warm water. Vyaghri Haritaki Avaleha includes *Solanum surattense*,

Terminalia chebula, ***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***, *Cinnamomum zylanicum, Cinnamomum tamala, Elleteria cardmomum, Mesua ferrea*. All the patients were kept under strict Pathyapalana (dietary & life-style modification) during the treatment. The observation on effect of therapy was encouraging and showed less recurrence. When the individualized overall effect of therapy were considered highest number of patient (82.60%) got Moderate positive response, 8.69% was observed with Mild positive response, and 8.69% of patients were observed Unchanged. 86.96% of the patients had no recurrence of the symptoms during the follow up period while 13.04% of the patients had recurrence but with lesser frequency and intensity may due to Rasayana (rejuvenation) effect of the drug on Pranavaha srotas.

47. Chaudhary, S. A., K. Patel, V. Kori and S. Rajagopala (1014). "**Management of doshika kasa in sub-acute and chronic stage with vyaghri haritaki avaleha in children.**" Ayurpharm Int J Ayur Alli Sci **3**(4): 97 - 111.

Respiratory Tract Infections (RTI) accounting about more than 50% of patients attending pediatric OPD as cough is the most frequent symptom of respiratory diseases majority of the patients' present recurrent cough as the manifestation of recurrent respiratory disease. From the Ayurvedic point of view, the descriptions about the disease Kasa clearly correlates with cough. Moreover the pathophysiology of Kasa almost exactly correlates the mechanism of cough reflex. It is important to treat any disease in childhood age at the earliest as it may hamper the Growth and development of child. Long standing disease affects the immunity and chronicity of the Kasa leads to Kshaya which has multi-system involvement. Due to disease, school absenteeism and expenditures of medicine are the burden on the society. As Kasa is Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, clinical study was undertaken on Kasa in sub-acute and chronic stage for duration of 4 weeks and also with follow-up of 4 weeks. The drug Vyaghri Haritaki Avaleha was given orally with luke warm water. Vyaghri Haritaki Avaleha includes *Solanum surattense*, ***Terminalia chebula***, ***Zingiber officinale***, ***Piper nigrum***, ***Piper longum***, *Cinnamomum zylanicum, Cinnamomum tamala, Elleteria cardmomum*, and *Mesua ferrea*. All the patients were kept under strict Pathyapalana (dietary & life-style modification) during the treatment. The observation on effect of therapy was encouraging and showed less recurrence. When the individualized overall effect of therapy were considered highest number of patient (82.60%) got Moderate positive response, 8.69% was observed with Mild positive response, and 8.69% of patients were observed Unchanged. 86.96% of the patients had no recurrence of the symptoms during the follow up period while 13.04% of the patients had recurrence but with lesser frequency and intensity may due to Rasayana (rejuvenation) effect of the drug on Pranavaha srotas.

48. Chaudhari, V., M. Rajagopala, S. Mistry and D. Vaghela (2010). "**Role of Pradhamana Nasya and Trayodashanga Kwatha in the management of Dushta Pratishyaya with special reference to chronic sinusitis.**" AYU **31**(3): 325-331.

Dushta Pratishyaya is the chronic stage of Pratishyaya, which occurs due to neglect or improper management of the disease Pratishyaya. In modern science, chronic

sinusitis can be correlated with Dushta Pratishyaya on the basis of the signs, symptoms, complications, and prognosis. Changing lifestyles, rapid urbanization, and the increase in cases of antibiotic resistance are responsible for the rise in the prevalence of sinusitis. In the present clinical study, 37 patients were registered and were randomly divided into three groups: A, B, and C; of the 37 patients, 31 completed the full course of treatment. In group A, Trayodashanga Kwatha with Madhu was given orally; in group B, Pradhamana Nasya with ***Trikatu*** + ***Triphala*** Churna was administered; and in group C (combined group), Pradhamana Nasya was administered initially, followed by oral Trayodashanga Kwatha with Madhu. Acharya Charaka has advised a combination of ***Trikatu*** (***Zingiber officinale***, ***Piper longum***, ***Piper nigrum***) and ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) Churna for Pradhamana Nasya in the context of Pratishyaya Chikitsa. In group A, complete relief was observed in 10% of the patients; in group B, marked improvement was observed in 81.82% of patients; and in group C, marked relief was observed in 60% of patients. In comparison to other groups (Group A and Group B), Group C showed percentage wise better results in most of the symptoms.

49. Chengappa, K. N. R., C. R. Bowie, P. J. Schlicht, D. Fleet, J. S. Brar and R. Jindal (2013). "**Randomized placebo-controlled adjunctive study of an extract of *Withania somnifera* for cognitive dysfunction in bipolar disorder.**" Journal of Clinical Psychiatry **74**(11): 1076-1083.

Cognitive impairments contribute significantly to inadequate functional recovery following illness episodes in bipolar disorder, yet data on treatment interventions are sparse. Authors assessed the cognitive effects of a standardized extract of the medicinal herb ***Withania somnifera*** (WSE) in bipolar disorder. Sixty euthymic subjects with DSM-IV bipolar disorder were enrolled in an 8-week, double-blind, placebo-controlled, randomized study of WSE (500 mg/d) as a procognitive agent added adjunctively to the medications being used as maintenance treatment for bipolar disorder. Study enrollment and data analyses were completed between December 2008 and September 2012. Cognitive testing at baseline and 8 weeks assessed primary efficacy outcomes. Psychopathology and adverse events were monitored at scheduled visits. Fifty-three patients completed the study (WSE, n = 24; placebo, n = 29), and the 2 groups were matched in terms of demographic, illness, and treatment characteristics. Compared to placebo, WSE provided significant benefits for 3 cognitive tasks: digit span backward (P = .035), Flanker neutral response time (P = .033), and the social cognition response rating of the Penn Emotional Acuity Test (P = .045). The size of the WSE treatment effect for digit span backward was in the medium range (Cohen d = 0.51; 95% CI, 0.25-0.77). None of the other cognitive tasks showed significant betweengroup differences. Mood and anxiety scale scores remained stable, and adverse events were minor. Although results are preliminary, WSE appears to improve auditory-verbal working memory (digit span backward), a measure of reaction time, and a measure of social cognition in bipolar disorder. Given the paucity of data for improving cognitive capacity in bipolar disorder, WSE offers promise, appears to have a benign side-effects profile, and merits further study.

50. Chopra, A., P. Lavin, B. Patwardhan and D. Chitre (2004). "**A 32-week randomized, placebo-controlled clinical evaluation of RA-11, an Ayurvedic drug, on osteoarthritis of the knees.**" Journal of Clinical Rheumatology **10**(5): 236-245.

The ancient Indian (Asian) Ayurvedic medicinal system uses herbomineral drugs to treat arthritis. Despite centuries of use, very few have been tested by drug trials. RA-11 (ARTREX, MENDAR), a standardized multiplant Ayurvedic drug (***Withania somnifera***, *Boswellia serrata*, ***Zingiber officinale***, and *Curcuma longa*) is currently used to treat arthritis. The objective of this study was to evaluate the efficacy and safety of RA-11 in patients with symptomatic osteoarthritis (OA) of the knees. Methods: A total of 358 patients with chronic knee pain were screened free-of-cost in "arthritis camps" in an Indian metropolis. Ninety patients with primary OA of the knees (ACR classification; Arthritis Rheum 1986;29:1039-1049) were found eligible (postanalgesic washout pain visual analog score [VAS] ≥40 mm in either or both knees on body weight-bearing activities) to enroll into a randomized, double-blind, placebo-controlled, parallel efficacy, single-center, 32-week drug trial (80% power to detect 25% difference, P = 0.05, 2-sided). Concurrent analgesics/nonsteroidal antiinflammatory drugs and steroids in any form were not allowed. Lifestyle and/or dietary restrictions, as per routine Ayurveda practices, were not imposed. Pain VAS (maximum pain in each knee recorded by the patient during the preceding 48 hours) and modified WOMAC (Western Ontario McMaster University OA Index, Likert scale, version 3.0) were the primary efficacy variables. The WOMAC section on "physical function difficulty" was modified for Indian use and validated before the trial. Routine laboratory testing was primarily done to monitor drug safety. At baseline, the groups (active = 45, placebo = 45) were well matched for several measures (mean pain VAS: active = 6.17; placebo = 6.5). Results: 1) Efficacy: Compared with placebo, the mean reduction in pain VAS at week 16 (active = 2.7, placebo = 1.3) and week 32 (active = 2.8, placebo = 1.8) in the active group was significantly (P <0.05, analysis of variance [ANOVA]) better. Similarly, the improvement in the WOMAC scores at week 16 and week 32 were also significantly superior (P <0.01, ANOVA) in the active group. 2) Safety: Both the groups reported mild adverse events (AE) without any significant difference. 3) Withdrawals: Twenty-eight patients were discontinued. None reported drug-related toxicity. The majority failed follow up/compliance. No differences were observed between the groups. This controlled drug trial demonstrates the potential efficacy and safety of RA-11 in the symptomatic treatment of OA knees over 32 weeks of therapy.

51. Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, G. Narsimulu, S. Sarmukaddam and B. Patwardhan (2012). "**Evaluating higher doses of Shunthi - Guduchi formulations for safety in treatment of osteoarthritis knees: A Government of India NMITLI arthritis project.**" Journal of Ayurveda and Integrative Medicine **3**(1): 38-44.

Results of an exploratory trial suggested activity trends of ***Zingiber officinale***-***Tinospora cordifolia*** (platform combination)-based formulations in the treatment of Osteoarthritis (OA) Knees. These formulations were "platform combination+***Withania somnifera***+*Tribulus terrestris*0" (formulation B) and "platform combination+Emblica officinale" (formulation C). This paper reports safety of these formulations when used in higher doses (1.5-2 times) along with Sallaki Guggul and Bhallataka Parpati (a *Semecarpus anacardium* preparation). Ninety-two

patients with symptomatic OA knees were enrolled in a 6 weeks investigator blind, randomized parallel efficacy 4-arm multicenter drug trial. The 4 arms were (I) formulation B, 2 t.i.d.; (II) formulation B, 2 q.i.d.; (III) platform combination+Sallaki Guggul; (IV) Bhallataka Parpati+formulation C. A detailed enquiry was carried out for adverse events (AE) and drug toxicity as per a priori check list and volunteered information. Laboratory evaluation included detailed hematology and metabolic parameters. Patients were examined at baseline, first and fourth weeks, and on completion. Standard statistical program (SPSS version 12.5) was used for analysis. Results: None of the patients reported serious AE or withdrew due to any drug-related toxicity. Mild gut-related (mostly epigastric burning) AE was reported. A mild increase in liver enzymes [serum glutamic pyruvate transaminase (SGPT), serum glutamic oxaloacetic transaminase (SGOT)] without any other hepatic abnormality was reported in 2 patients (group IV). Other laboratory parameters remained normal. The mean improvement in active pain visual analog scale (1.4, CI 0.5-2.22), WOMAC (functional activity questionnaire) pain score (1.37, CI 0.22-2.5), and urinary C-TAX (cartilage collagen breakdown product) assay was maximum (NS) in group IV. Lower dose group I showed numerically superior improvement compared with higher dose group II. The results suggested that despite higher doses, standardized Ayurvedic formulations demonstrated a good safety profile. An improved efficacy and likely chondroprotective effect was shown by group IV intervention. A confirmatory drug trial with adequate power and sample size was planned based on the learning from this trial.

52. Chopra, A., M. Saluja, G. Tillu, S. Sarmukkaddam, A. Venugopalan, G. Narsimulu, R. Handa, V. Sumantran, A. Raut, L. Bichile, K. Joshi and B. Patwardhan (2013). "**Ayurvedic medicine offers a good alternative to glucosamine and celecoxib in the treatment of symptomatic knee osteoarthritis: A randomized, double-blind, controlled equivalence drug trial.**" Rheumatology **52**(8): 1408-1417.

To demonstrate clinical equivalence between two standardized Ayurveda (India) formulations (SGCG and SGC), glucosamine and celecoxib (NSAID). Ayurvedic formulations (extracts of ***Tinospora cordifolia***, ***Zingiber officinale***, ***Emblica officinalis***, *Boswellia serrata*), glucosamine sulphate (2 g daily) and celecoxib (200mg daily) were evaluated in a randomized, double-blind, parallel-efficacy, four-arm, multicentre equivalence drug trial of 24 weeks duration. A total of 440 eligible patients suffering from symptomatic knee OA were enrolled and monitored as per protocol. Primary efficacy variables were active body weight-bearing pain (visual analogue scale) and modified WOMAC pain and functional difficulty Likert score (for knee and hip); the corresponding a priori equivalence ranges were ∓1.5 cm, ∓2.5 and ∓8.5. Results. Differences between the intervention arms for mean changes in primary efficacy variables were within the equivalence range by intent-to-treat and per protocol analysis. Twenty-six patients showed asymptomatic increased serum glutamic pyruvic transaminase (SGPT) with otherwise normal liver function; seven patients (Ayurvedic intervention) were withdrawn and SGPT normalized after stopping the drug. Other adverse events were mild and did not differ by intervention. Overall, 28% of patients withdrew from the study. In this 6-month controlled study of knee OA, Ayurvedic formulations (especially SGCG) significantly reduced knee pain and improved knee function and were equivalent to glucosamine and celecoxib. The

unexpected SGPT rise requires further safety assessment. Trial registration: Clinical Drug Trial Registry - India, www.ctri.nic.in, CTRI/2008/091/000063.

53. Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, G. Narsimulu, R. Handa, L. Bichile, A. Raut, S. Sarmukaddam and B. Patwardhan (2012). "**Comparable efficacy of standardized Ayurveda formulation and hydroxychloroquine sulfate (HCQS) in the treatment of rheumatoid arthritis (RA): A randomized investigator-blind controlled study.**" Clinical Rheumatology **31**(2): 259-269.

Hydroxychloroquine sulfate (HCQS) is a popular disease-modifying antirheumatic drug (DMARD) despite modest efficacy and toxicity. Ayurveda (ancient India medicinal system) physicians treat rheumatoid arthritis (RA) with allegedly safer herbal formulations. Authors report a head-to-head comparison in an exploratory drug trial. The objective is to compare standardized Ayurvedic formulations and HCQS in the treatment of RA. One hundred twenty-one patients with active moderately severe RA (ACR 1988 classified) were randomized into a 24-week investigator-blind, parallel efficacy, three-arm (two Ayurvedic and HCQS) multicenter drug trial study; polyherb (***Tinospora cordifolia*** and ***Zingiber officinale*** based) and monoherb (*Semecarpus anacardium*). Study measures included joint counts (pain/tenderness and swelling), pain visual analogue scale, global disease assessments, and health assessment questionnaire. Oral meloxicam (fixed-dosage schedule) was prescribed to all patients during the initial 16 weeks. Patients on prednisolone could continue a fixed stable dose (<7.5 mg daily). Rescue oral use of paracetamol was permitted and monitored. All groups matched well at baseline. An intent-to-treat analysis (ANOVA, significance $P<0.05$) did not show significant differences by treatment groups. In the polyherb, monoherb, and HCQS arms, 44%, 36%, and 51%, respectively, showed ACR 20 index improvement. Several efficacy measures improved significantly in the HCQS and polyherb groups with no difference between the groups (corrected P). However, the latter was individually superior to monoherb. Only mild adverse events (gut and skin, and none withdrew) were reported with no differences between the groups. Forty-two patients dropped out. This preliminary drug trial controlled for HCQS demonstrated a standardized Ayurvedic polyherb drug to be effective and safe in controlling active RA. A better-designed study with a longer evaluation period is recommended.

54. Chopra, A., M. Saluja, G. Tillu, A. Venugopalan, S. Sarmukaddam, A. K. Raut, L. Bichile, G. Narsimulu, R. Handa and B. Patwardhan (2011). "**A randomized controlled exploratory evaluation of standardized ayurvedic formulations in symptomatic osteoarthritis knees: A Government of India NMITLI project.**" Evidence-based Complementary and Alternative Medicine **2011:** Article ID 724291.

The multidisciplinary "New Millennium Indian Technology Leadership Initiative" Arthritis Project was undertaken to validate Ayurvedic medicines. Herbal formulations in popular use were selected by expert consensus and standardized using modern tools. Clinical strategy evolved from simple exploratory evaluations to better powered statistically designed drug trials. The results of the first drug trial are presented here. Five oral formulations (coded A, B, C, D and E), with a common base of ***Zingiber officinale*** and ***Tinospora cordifolia*** with a maximum of four plant extracts, were evaluated; with placebo and glucosamine as controls. 245 patients suffering from

symptomatic OA knees were randomized into seven arms (35 patients per arm) of a double blind, parallel efficacy, multicentric trial of sixteen weeks duration. The groups matched well at baseline. There were no differences for patient withdrawals (17.5%) or adverse events (AE) of mild nature. Intention-to-treat efficacy analysis, demonstrated no significant differences (P<.05) for pain (weight bearing) and WOMAC questionnaire (knee function); placebo response was high. Based on better pain relief, significant (P<.05) least analgesic consumption and improved knee status, "C" formulation was selected for further development. Controlled exploratory drug trials with multiple treatment arms may be used to economically evaluate several candidate standardized formulations.

55. Choudhary, B., A. Shetty and D. G. Langade (2015). "**Efficacy of Ashwagandha (*Withania somnifera* [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults.**" AYU **36**(1): 63-68.

Ashwagandha (***Withania somnifera*** [L.] Dunal) has been traditionally used for various actions ranging from vitalizer, improve endurance and stamina, promote longevity, improve immunity, and male and female fertility. However, clinical studies are needed to prove the clinical efficacy of this herb, especially in cardiovascular endurance and physical performance. This prospective, double-blind, randomized, and placebo-controlled study evaluated the efficacy of Ashwagandha roots extract in enhancing cardiorespiratory endurance and improving the quality of life (QOL) in 50 healthy male/female athletic adults. Cardiorespiratory endurance was assessed by measuring the oxygen consumption at peak physical exertion (VO2max) levels during a 20 m shuttle run test. The World Health Organization self-reported QOL questionnaire (physical health, psychological health, social relationships, and environmental factors) was used to assess the QOL. Student's t-test was used to compare the differences in a mean and change from baseline VO2max levels, whereas Wilcoxon signed-rank test was used to assess changes in QOL scores from baseline in the two groups. Results: There was a greater increase from baseline (P < 0.0001) in the mean VO2max with KSM-66 Ashwagandha (n = 24) compared to placebo (n = 25) at 8 weeks (4.91 and 1.42, respectively) and at 12 weeks (5.67 and 1.86 respectively). The QOL scores for all subdomains significantly improved to a greater extent in the Ashwagandha group at 12 weeks compared to placebo (P < 0.05). The findings suggest that Ashwagandha root extract enhances the cardiorespiratory endurance and improves QOL in healthy athletic adults.

56. Chuangsuwanich, A. and K. Jongjamfa (2014). "**The efficacy of combined herbal extracts gel preparation in the prevention of postsurgical hypertrophic scar formation.**" Dermatology and Therapy **4**(2).

The objective of preventing surgical scar formation is to improve the quality of life for patients. Many medical products have been used in preventing hypertrophic scarring but an optimal treatment method has not been established yet. At the present, there are several studies demonstrating the potential of herbs in scar prevention. The purpose of this study was to evaluate the efficacy of combined herbal extracts gel (CHG) in the prevention of surgical scar formation. Methods: All the patients who underwent bilaterally symmetric surgical procedures were selected using inclusion and exclusion criteria and were then treated with both the CHG (CHG group) and

placebo gel. The combined herbal extract gel (CHG) is a composition of *Allium cepa* (12% w/w), *Centella asiatica* (5% w/w), *Aloe vera* (4% w/w), ***Phyllanthus emblica*** (1.5% w/w), and *Tamarindus indica* (1.5% w/w) extract. Each gel was applied on separate scars twice daily for 12 weeks. The scars were photographed and evaluated using Patient and Observer Scar Assessment Scale (PSAS and OSAS, respectively). The CHG-treated scars showed lower median PSAS scores than the placebo group in color, stiffness, thickness, irregularity, and overall scores, with statistically significant difference at 12 weeks. For OSAS, the scars in the CHG group showed lower median scores than the placebo group in pigmentation, thickness, and overall scores at 12 weeks. The median OSAS scores in vascularity, relief, and pliability differed from placebo group and were statistically significant at 8 weeks. No side effects were observed in either group. The CHG might be effective in the prevention of surgical scarring.

57. Colucci, R., F. Dragoni, R. Conti, L. Pisaneschi, L. Lazzeri and S. Moretti (2015). "**Evaluation of an oral supplement containing *Phyllanthus emblica* fruit extracts, vitamin E, and carotenoids in vitiligo treatment.**" Dermatologic Therapy **28**(1): 17-21.

Phyllanthus emblica (***syn. Emblica officinalis***), vitamin E, and caroteinods are compounds showing antioxidative, anti-inflammatory, and repigmenting effects, whose role in vitiligo treatment has not been evaluated so far. Sixty-five subjects (group A) were treated with one tablet of an oral supplement containing *P. emblica* (100 mg), vitamin E (10 mg), and carotenoids (4.7 mg) three times/day for 6 months and compared with a control group (group B, 65 patients), which instead was not treated with antioxidants. Both groups were simultaneously treated with a comparable topical therapy and/or phototherapy. After a 6 months follow-up, a significantly higher number of patients in group A had a mild repigmentation on the head/neck regions ($p = 0.019$) and on the trunk (trend, $p = 0.051$). The number of patients who presented no repigmentation in head/neck, trunk, upper, and lower limbs was significantly higher in group B (respectively, $p = 0.009$, $p = 0.001$, $p = 0.001$, $p = 0.025$). Moreover, group B patients showed higher signs of inflammation ($p = 0.002$), a more rapid growth of the lesions ($p = 0.039$), a higher percentage of worsening disease ($p = 0.003$), and more erythema ($p = 0.059$), whereas group A patients showed a higher percentage of steady disease ($p = 0.065$). These results suggest that the supplement with antioxidants in patients with vitiligo might represent a valuable instrument to increase the effectiveness of other vitiligo treatments.

58. Cooley, K., O. Szczurko, D. Perri, E. J. Mills, B. Bernhardt, Q. Zhou and D. Seely (2009). "**Naturopathic care for anxiety: A randomized controlled trial ISRCTN78958974.**" PLoS ONE **4**(8).

Anxiety is a serious personal health condition and represents a substantial burden to overall quality of life. Additionally anxiety disorders represent a significant cost to the health care system as well as employers through benefits coverage and days missed due to incapacity. This study sought to explore the effectiveness of naturopathic care on anxiety symptoms using a randomized trial. Employees with moderate to severe anxiety of longer than 6 weeks duration were randomized based on age and gender to receive naturopathic care (NC) ($n = 41$) or standardized psychotherapy

intervention (PT) (n = 40) over a period of 12 weeks. Blinding of investigators and participants during randomization and allocation was maintained. Participants in the NC group received dietary counseling, deep breathing relaxation techniques, a standard multi-vitamin, and the herbal medicine, ashwagandha (***Withania somnifera***) (300 mg b.i.d. standardized to 1.5% withanolides, prepared from root). The PT intervention received psychotherapy, and matched deep breathing relaxation techniques, and placebo. The primary outcome measure was the Beck Anxiety Inventory (BAI) and secondary outcome measures included the Short Form 36 (SF-36), Fatigue Symptom Inventory (FSI), and Measure Yourself Medical Outcomes Profile (MY-MOP) to measure anxiety, mental health, and quality of life respectively. Participants were blinded to the placebo-controlled intervention. Seventy-five participants (93%) were followed for 8 or more weeks on the trial. Final BAI scores decreased by 56.5% ($p<0.0001$) in the NC group and 30.5% ($p<0.0001$) in the PT group. BAI group scores were significantly decreased in the NC group compared to PT group ($p=0.003$). Significant differences between groups were also observed in mental health, concentration, fatigue, social functioning, vitality, and overall quality of life with the NC group exhibiting greater clinical benefit. No serious adverse reactions were observed in either group. Many patients seek alternatives and/or complementary care to conventional anxiety treatments. To date, no study has evaluated the potential of a naturopathic treatment protocol to effectively treat anxiety. Knowledge of the efficacy, safety or risk of natural health products, and naturopathic treatments is important for physicians and the public in order to make informed decisions. Interpretation: Both NC and PT led to significant improvements in patients' anxiety. Group comparison demonstrated a significant decrease in anxiety levels in the NC group over the PT group. Significant improvements in secondary quality of life measures were also observed in the NC group as compared to PT. The whole system of naturopathic care for anxiety needs to be investigated further including a closer examination of the individual components within the context of their additive effect.

59. Costa, A., M. De Oliveira Pereira, T. Abdalla Moisés, T. Cordero, A. R. Dias Silva, F. T. P. Amazonas, F. Bentivoglio and E. S. Pegas Pereira (2011). "**Evaluation of quality of life improvement in melasma patients, measured by the MELASQoL following the use of a botanical combination based on *Bellis perennis*, *Glycyrrhiza glabra* *Phyllanthus emblica*.**" Surgical and Cosmetic Dermatology **3**(3): 207-212.

Melasma is a common hypermelanosis that mainly affects women and has a negative impact on the quality of life. It is a chronic and recurrent condition, and a number of treatments have already been proposed. Assessment of quality of life for women with melasma before and after treatment with botanical extracts and hydroquinone. A clinical, phase IV, randomized, blinded study was conducted at a clinical research institute. Women (n = 56) aged 18-60, with phototypes I-IV, were randomized into two groups (epidermal or mixed melasma). The Melasma Quality of Life Scale was used to compare the patients' quality of life before and after the use of Bellis perennis, Glycyrrhiza glabra and ***Phyllanthus emblica*** botanical extracts twice a day (Group A), or 2% hydroquinone used at night (Group B). The Melasma Area and Severity Index was used to assess the treatments' efficacy. Results: Appearance, frustration, embarrassment and feeling less attractive were the Melasma Quality of

Life Scale variables that had the greatest negative impact on quality of life at the beginning of the study. After 60 days of treatment, there was improvement in all MELASQoL aspects, with no statistical differences between the two groups. The improvement in melasma patients' self esteem provided by the use of the botanical extracts matched that of 2% hydroquinone.

60. Dahanukar, S. A., U. M. Thatte, N. N. Rege and R. D. Bapat (1990). "**Immunotherapeutic activity of *Tinospora cordifolia*.**" European Journal of Pharmacology **183**(2): 608.

In patients of obstructive jaundice who received TC (16 mg/kg) during the course of percutaneous transhepatic biliary drainage and for 15 days following surgery in addition to conventional treatment the neutrophil phagocytic function was 30.71 f 4.03% and intraceliuiar bactericidal capacity was 31.45 + 5.74% (P < 0.05). There was no mortality in this group. (n = 15). The group (n = 15) which received only conventional treatment during intervention exhibited persistent depression of neutriphil function (phagocytic function 21.1 + 3.7% as compared to normal control, 30.7 f 5.1%; intracellular bactericidal capacity was 20.85 + 4.5% as compared to normal control 26.41 f 4.5% P < 0.05). Mortality was 70%. This double blind randomised placebo control trial was conducted in patients with perforative peritonitis and those with local sepsis. After basal immunological and hematological analysis, clinical monitoring was done and patients were graded. The patients received either TC/Placebo as a supplement to antimicrobial therapy. Improvement in neutrophil and montcyte function associated with early wound healing was observed in patients treated with TC. In view of variety of immunosuppressive and infective states that this plant can modify along with its oral efficacy and significant lack of adverse effects, ***Tinospora cordifolia*** shows promise as useful immunotherapeutic agent.

61. Daily, J. W., X. Zhang, D. S. Kim and S. Park (2015). "**Efficacy of Ginger for alleviating the symptoms of primary dysmenorrhea: A systematic review and meta-analysis of randomized clinical trials.**" Pain Medicine (DOI: 10.1111/pme.12853 in press).

There has been no attempt to date to synthesize the available evidence for the efficacy of ginger for treating primary dysmenorrhea. This systematic review evaluates the current evidence for the effectiveness of ginger for treating primary dysmenorrhea. Literature searches were conducted using 12 electronic databases including PubMed, EMBASE, Cochrane Library, Korean databases, Chinese medical databases, and Indian scientific database. Search terms used were: "ginger" or "***Zingiber officinale***" and "dysmenorrhea" and "pain." Studies using ginger as a treatment of primary dysmenorrhea were considered for inclusion. The major outcome of primary dysmenorrhea was assessed using a pain visual analogue score (PVAS). Initial searches yielded 29 articles. Of these original results, seven met specific selection criteria. Four of the RCTs compared the therapeutic efficacy of ginger with a placebo during the first 3–4 days of the menstrual cycle and were included in the meta analysis. The meta-analysis of these data showed a significant effect of ginger in reducing PVAS in subjects having primary dysmenorrhea (risk ratio, −1.85; 95% CI of −2.87, −0.84, P = 0.0003). Six RCTs out of 7 exhibited low to moderate risk of bias. Collectively these RCTs provide suggestive evidence for the effectiveness of 750–2000

mg ginger powder during the first 3–4 days of menstrual cycle for primary dysmenorrhea.

62. Daily, J. W., M. Yang, D. S. Kim and S. Park (2015). "**Efficacy of ginger for treating Type 2 diabetes: A systematic review and meta-analysis of randomized clinical trials.**" Journal of Ethnic Foods **2**(1): 36-43.

Few clinical trials have investigated the antidiabetic effects of ginger to date. Several recent clinical trials published in 2013 and 2014, although small, have added contradictory but compelling new evidence about the use of ginger in treating diabetes in humans. Therefore, a systematic review and meta-analysis was conducted to clarify the evidence for using ginger to treat diabetes. Five randomized clinical trials (RCTs) were identified and included in the meta-analysis. Four of the RCTs were considered high quality and lasted ≥8 weeks; one lasted only 30 days and was considered low quality. Outcomes measured included fasting blood glucose and insulin, homeostatic model assessment (HOMA)-insulin resistance (IR), and hemoglobin A1c (HbA1c) levels, and were assessed as mean differences in the meta-analysis. Ginger (***Zingiber officinale***) supplementation significantly lowered fasting blood glucose concentrations and HbA1c levels, but did not significantly lower fasting blood insulin or HOMA-IR. In conclusion, Ginger root supplementation significantly lowers blood glucose and HbA1c levels. When combined with dietary and lifestyle interventions it may be an effective intervention for managing Type 2 diabetes mellitus.

63. Debnath, P. K., J. Chattopadhyay, A. Mitra, A. Adhikari, M. S. Alam, S. K. Bandopadhyay and J. Hazra (2012). "**Adjunct therapy of Ayurvedic medicine with anti tubercular drugs on the therapeutic management of pulmonary tuberculosis.**" Journal of Ayurveda and Integrative Medicine **3**(3): 141-149.

Pulmonary tuberculosis (PTB) is an age old disease described in Vedic Medicine as 'Yakshma'. Later on, in Ayurveda it earned a prefix and found way into mythology as 'Rajayakshma'. After the discovery of streptomycin, the therapeutic management of PTB received a major breakthrough. The treatment module changed remarkably with the formulation of newer anti-tubercular drugs (ATD) with appreciable success. Recent resurgence of PTB in developed countries like United States posed a threat to the medical community due to resistant strains. Consequently, WHO looked toward traditional medicine. Literature reveals that Ayurvedic treatment of PTB was in vogue in India before the introduction of ATD with limited success. Records show that 2766 patients of PTB were treated with Ayurvedic drugs in a tertiary care hospital in Kolkata in the year 1933-1947. This study evaluated the toxicity reduction and early restoration by adjunct therapy of Ayurvedic drugs by increasing the bio-availability of ATDs. In the present study, treatment response of 99 patients treated with ATD as an adjunct with Aswagandha (***Withania somnifera***) and a multi-herbal formulation described in Chikitsa-sthana of Charaka samhita i.e. Chyawanprash were investigated. Chyawanprash contains ***Emblica officinalis***, ***Piper longum***, ***Withania somnifera***, ***Terminallia chebula***, ***Zingiber officinale***, ***Tinospora cordifolia*** among other ingredients. Hematological profile, sputum bacterial load count, immunoglobulin IgA and IgM, blood sugar, liver function test, serum creatinine were the assessed

parameters besides blood isoniazid and pyrazinamide, repeated after 28 days of treatment. The symptoms abated, body weight showed improvement, ESR values were normal, there was appreciable change in IgA and IgM patterns and significantly increased bioavailability of isoniazid and pyrazinamide were recorded. This innovative clinical study coupled with empowered research may turn out to be promising in finding a solution for the treatment of PTB.

64. Deshpande, A., S. Tandon and N. Deshpande (2014). "**Low resource screening method of pre-cancerous lesions and its reversal by *Triphala* in teen-age Indian population.**" AYU **35**(2): 160-167.

Cancer screening is the main weapon for early detection at a pre-invasive or premalignant stage. It has been reported that over 12 million people use some form of tobacco, which is one of the high risk factors and has hence become an alarming world-wide problem. Aim was to evaluate the effective diagnostic screening of disease in its early stage by inexpensive method and also to evaluate the effect of indigenous mouthrinse on reversal of pre-cancerous lesions. The screening for teenagers belonging to low socio-economic status was carried out. Suspected subjects were evaluated for the reversal of the lesions by use of Ayurvedic preparation as a mouthwash. From 13 to19 years working-child population of North India was selected for the study. Screening was performed by new method-visual inspection with acetic acid. The positive subjects were further investigated by pap smear and biopsy was done as a confirmatory histopathological report. In second phase, the subjects showing positive lesions were advised indigenous anti-cancer mouth rinse and its effect was evaluated after 6 month and 9 month of prescribing the rinse. The total 1095 children were screened (831 boys and 264 girls). Out of total 34 teenager boys were diagnosed, as acetowhite positive lesion. All the acetowhite positive lesions were found exclusively in males. Histological findings after 9 month use of ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***) mouth rinse revealed no changes in cells in 23 (85.2%), hyperkeratinization in 2 (7.4%), hyperkeratinization and spongiosis was evident in 1 (3.7%), mild pleomorphism in 1 (3.7%) patient. Comparative evaluation from 0-9 month showed statistically highly significant test ($P < 0.01$). Use of different forms of tobacco and betel nut showed convincing relationship between developments of oral pre-cancerous lesions. ***Triphala*** was found to have great potential for reversal of these lesions.

65. Dixit, K. S., S. Saxena, S. Vart, V. S. Narain, A. Mishra, A. Dixit and V. K. Puri (1999). "**CardiPro - A polyherbal preparation in the therapy of angina pectoris.**" Phytomedica **20**(1-2): 7-16.

Coronary Artery Disease (CAD) is one of the commonest causes of male adult morbidity and mortality the world over and its incidence rises with increasing age. Despite a number of modern drugs being available for the treatment of CAD, none of them is able to prevent disease progression or impending myocardial infarction (MI). However, Ancient Indian Medical Science (AIMS) cites several herbal preparations for this purpose. Taking lead from AIMS a polyherbal preparation CardiPro containing standardised extracts of *Terminalia arjuna*, ***Emblica officinalis***, ***Withania somnifera***, *Ocimum sanctum* and *Boerhaavia diffusa* was clinically tried in 29 cases of

chest pain out of which 17 were positive for Inducible Ischaemia on treadmilltest (TMT). The results show that the herbal formulation CardiPro ameliorates Angina symptoms and helps to reduce nitrate use significantly.

66. Donata, S., M. Kesavan Sr, K. Austin, K. Rajagopalan and R. Kuttan (1990). "**Clinical trial of certain ayurvedic medicines indicated in vitiligo.**" Ancient science of life **9**(4): 202-206.

An Ayurvedic preparation consisting of dried ginger (***Zingiber officinale***), black pepper (***Piper nigrum***), pippali (***Piper longum***) and leadwort root fermented in cow's urine was given internally and a paste made of several meical herbs including *Psoralea corylifolia* for external application was tried in patients with vitiligo. 4 out of 10 patients had relief within six months of treatment. Three patients had relief with adverse reaction on the skin and other did not respond. The preparations did not have any adverse effect in the body as seen from haematological parameters and biochemical tests.

67. Dongre, S., D. Langade and S. Bhattacharyya (2015). "**Efficacy and Safety of Ashwagandha (*Withania somnifera*) Root Extract in Improving Sexual Function in Women: A Pilot Study.**" BioMed Research International **2015**: Article ID 284154.

Many women experience sexual dysfunction where there are orgasm disorders and sexual difficulties. Ashwagandha (***Withania somnifera***) is known to improve the body's physical and psychological condition. The purpose of the study was to determine the efficacy and safety of a high-concentration ashwagandha root extract (HCARE) supplementation for improving sexual function in healthy females. In this pilot study, 50 study subjects were randomized to either (i) HCARE-treated group or (ii) placebo- (starch-) treated group. The subjects consumed either HCARE or placebo capsules of 300 mg twice daily for 8 weeks. Sexual function was assessed using two psychometric scales, the Female Sexual Function Index (FSFI) Questionnaire and the Female Sexual Distress Scale (FSDS), and by the number of total and successful sexual encounters. The analysis indicates that treatment with HCARE leads to significantly higher improvement, relative to placebo, in the FSFI Total score, FSFI domain score for "arousal", "lubrication", "orgasm", and "satisfaction", and also FSDS score and the number of successful sexual encounters at the end of the treatment. This study demonstrated that oral administration of HCARE may improve sexual function in healthy women. The present study is registered in the Clinical Trial Registry, Government of India, with a number CTRI/2015/07/006045.

68. Dubey, A. K., S. Rajagopala and K. S. Patel (2014). "**Comparative clinical efficacy of Ashtangavaleha and Vyaghreehareetakee Avaleha on Tamaka Shwasa (bronchial asthma) in children.**" AYU **35**(4): 384-390.

Tamaka Shwasa is a chronic inflammatory condition of the lung airways resulting in episodic airflow obstruction. This disease is more predominant in children and aged population. Apart from being the leading cause of hospitalization for children, it is one of the most important chronic conditions causing elementary school absenteeism. The parallel disease entity in contemporary medical science to this disorder is Bronchial Asthma. Aim: This study was aimed to evaluate the clinical efficacy of Ashtangavaleha and Vyaghreehareetakee Avaleha on Tamaka Shwasa (Bronchial Asthma) in Children. Materials and Methods: The study was therapeutic

interventional randomized clinical trial. Totally 100 patients suffering from Tamaka Shwasa were selected, and 74 patients completed the course of treatment. Patients were divided into two groups. Ashtangavaleha (***Zingiber officinale***, Nigella sativa, Pistacia integerrima, Myrica nagi, Madhu –Honey, ***Piper nigrum***, ***Piper longum***, Inula racemose, Trachyspermum Ammi) was administered in group AG and Vyaghreeharitaki Avaleha (containing ***Trikatu*** and ***Terminalia chebula*** among others) was administerd in group VG (5-15g in divided doses) for 8 weeks duration. Comaprative assesment of both the drugs was done on the signs and symptoms of the disease, pulmonary function test and quality of life parameters. Results: When the individualized overall effect of therapy was considered, more number of patients treated with Ashtangavaleha reached moderate improvement zone than the patients treated with Vyaghreehareetakee Avaleha. The trial showed a marginal better efficacy of Ashtangavaleha (66.66%) in comparison to Vyaghreehareetakee Avaleha (63.15%) on the overall condition of the patients even though the superiority was statistically insignificant (>0.05).

69. Dwivedi, R. and S. More (2011). "**A clinical study of Panchakola Siddha Yavagu in the management of Agnimandya.**" AYU **32**(1): 70-75.

This research is carried out with the aim to study Agnidipana effect of Panchakola Siddha Yavagu which comprises Pippali (***Piper longum***), Pippalimula (root of ***Piper longum***), Chavya (*Piper chaba* Hunter), Chitraka (*Plumbago zelynica*) and Nagara (***Zingiber officinale***) which are all in equal proportion processed in six times of water. A randomized open clinical trial on 47 patients of Agnimandya has been screened on the basis of clinical findings and the patients were allocated to two groups. Group A having 29 cases received the trial drug (Panchakola Siddha Yavagu) and 18 cases in Group B received simple Yavagu with roasted rice powder as the control group. Special scoring pattern was done for the assessment of Agnimandya state. Complete cure of the patient was found in 17.24% of the patients, 34.48% patients were improved moderately as well as markedly, whereas mild improvement was observed in 13.80% patients by treatment with Panchakola Yavagu.

70. Eberhart, L. H. J., R. Mayer, O. Betz, S. Tsolakidis, W. Hilpert, A. M. Morin, G. Geldner, H. Wulf and W. Seeling (2003). "**Ginger does not prevent postoperative nausea and vomiting after laparoscopic surgery.**" Anesthesia and Analgesia **96**(4): 995-998.

The potential antiemetic effect of two different oral doses of the herbal remedy ginger (***Zingiber officinale***) to prevent postoperative nausea and vomiting in 180 patients undergoing gynecologic laparoscopy was investigated in this randomized, double-blinded trial. Ginger failed to reduce the incidence of postoperative nausea and vomiting after these procedures.

71. Ebrahimzadeh Attari, V., M. Asghari Jafarabadi, M. Zemestani and A. Ostadrahimi (2015). "**Effect of *Zingiber officinale* supplementation on obesity management with respect to the uncoupling protein 1 -3826A>G and ß3-adrenergic Receptor Trp64Arg polymorphism.**" Phytotherapy Research **28**(7): 1032–1039.

The present study aimed to investigate the effect of ginger (***Zingiber officinale***) supplementation on some obesity-associated parameters, with nutrigenetics approach. Accordingly, 80 eligible obese women (aged 18-45years) were randomly

assigned to receive either ginger (2-g ginger rhizomes powder as two 1-g tablets per day) or placebo supplements (corn starch with the same amount) for 12weeks. Subjects were tested for changes in body weight, body mass index, waist and hip circumferences, body composition, appetite score, and dietary intake. Moreover, participants were genotyped for the -3826A>G and Trp64Arg polymorphisms of uncoupling protein 1 and ß3-adrenergic receptor genes, respectively. Over 12weeks, ginger supplementation resulted in a slight but statistically significant decrease in all anthropometric measurements and total appetite score as compared with placebo group, which were more pronounced in subjects with the AA genotype for uncoupling protein 1 and Trp64Trp genotype for ß3-adrenergic receptor gene. However, there was no significant difference in changes of body composition and total energy and macronutrients intake between groups. In conclusion, these findings suggest that ginger consumption has potential in managing obesity, accompanying with an intervention-genotype interaction effect. However, further clinical trials need to explore ginger's efficacy as an anti-obesity agent in the form of powder, extract, or its active components.

72. Ebrahimzadeh Attari, V., A. Ostadrahimi, M. Asghari Jafarabadi, S. Mehralizadeh and S. Mahluji (2015). "**Changes of serum adipocytokines and body weight following *Zingiber officinale* supplementation in obese women: a RCT.**" European Journal of Nutrition (in press)

The present randomized, double-blind, placebo-controlled study aimed to evaluate the effect of ***Zingiber officinale*** (ginger) consumption on some metabolic and clinical features of obesity. Methods: Eighty eligible obese women (aged 18–45 years) were randomly assigned to either ginger or placebo groups (receiving 2 g/day of ginger powder or corn starch as two 1 g tablets) for 12 weeks. Body mass index (BMI) and body composition were assessed every 4 weeks, and serum levels of leptin, adiponectin, resistin, insulin and glucose were determined before and after intervention. The homeostasis model assessment of insulin resistance (HOMA-IR) and quantitative insulin sensitivity check index (QUICKI) were also calculated. Results: Ginger consumption significantly decreased BMI, serum insulin and HOMA-IR index, along with increasing QUICKIs as compared to the placebo. Moreover, significant reductions in serum leptin, resistin and glucose were observed in both groups, especially in ginger group with nonsignificant differences between groups. The body composition and serum levels of adiponectin were not significantly changed in study groups. In conclusion, these findings demonstrate a minor beneficial effect of 2 g ginger powder supplementation for 12 weeks on weight loss and some metabolic features of obesity. However, given the lack of data in this area, ongoing clinical trials are needed to further explore ginger’s effectiveness.

73. Faizal, P., S. Suresh, R. Satheesh Kumar and K. T. Augusti (2009). "**A study on the hypoglycemic and hypolipidemic effects of an ayurvedic drug Rajanyamalakadi in diabetic patients.**" Indian Journal of Clinical Biochemistry **24**(1): 82-87.

A study was undertaken for evaluating the hypoglycemic and hypolipidemic effects of an ayurvedic medicine "Rajanyamalakadi" containing *Curcuma longa*, ***Emblica officinalis*** and *Salacia oblonga* in type II diabetic patients over a period of 3 months. Ethical committee consent for the study was given by the Director, Indian Systems of

Medicine, Kerala. A total of 43 patients with established diabetes mellitus as adjudged from clinical features and FBS values, appeared for the camp (Age group 35-75 yrs). An informed consent for the study was obtained from each patient. The clinical proforma was given to each patient to collect data such as height, weight, diet pattern, previous history of illness etc. The ongoing antidiabetic medications were stopped under medical supervision and the patients were provided with 'Rajanyamalakadi' tablets (dose 1-2 tablets each weighing 500mg). The dosage of the drug was decided by the supervising medical officer on a case to case basis, taking note of the clinical conditions and responsiveness of the patients. The patients were monitored for three months, who were divided into 6 groups based on their age and again into two groups, 5 & 6, based on their mean FBS values. ie; Normal Persons, Diabetics of age groups 35-45yrs, 46-55yrs, >55yrs and those with FBS < 145.9 mg% and > 145.9 mg%. The Ayurvedic medicine "Rajanyamalakadi" has showed significant antidiabetic, hypolipidemic and antioxidant effects. In addition to that significant ameliorating effects on the elevated serum AST and ALT activities were also demonstrated by the treatment. The nutraceuticals present in the drug like Terpenoids, Polyphenols, Curcumin etc are responsible for the medicinal effects.

74. Farag, N. H. and P. J. Mills (2003). "**A randomized-controlled trial of the effects of a traditional herbal supplement on sleep onset insomia.**" Complementary Therapies in Medicine **11**(4): 223-225.

Objectives were to study the effectiveness and safety of a traditional herbal supplement used for sleep onset insomnia. Design: A double-blind, randomized, placebo-controlled, cross-over study. Setting: A total of 25 healthy volunteers (20-65 years of age) suffering from sleep onset insomnia were recruited from the general population. Intervention: A traditional Ayurvedic supplement formulated to reduce sleep onset insomnia containing species such as *Convolvulus pluricalis* extract, ginger extract (***Zingiber officinale***), Glycyrrhiza extract, musk, ***Piper nigrum*** extract, Rosa centifolia extract, ***Tinospora cordifolia*** extract, and ***Withania somnifera*** extract. Main Outcome Measure: Sleep latency. Results: The supplement led to a statistically significant decrease in reported sleep latency of 16.72 min (S.D. = 44.8) as compared to placebo (P = 0.003). There were no self-reported side effects. The findings suggest that traditional herbal supplements may be of significant benefit to patients suffering from sleep onset insomnia while avoiding the negative side effects of commonly prescribed hypnotics.

75. Fatima, N., U. Pingali and R. Pilli (2014). "**Evaluation of *Phyllanthus emblica* extract on cold pressor induced cardiovascular changes in healthy human subjects.**" Pharmacognosy Research **6**(1): 29-35.

Acute and chronic stress is a risk factor for the development and progression of coronary artery disease. Increased arterial stiffness is an independent marker for cardiovascular disease. Cold pressor test (CPT) is known to be associated with substantial activation of the autonomic nervous system. The aim of this study was to evaluate the effect of ***Phyllanthus emblica*** extract on cold pressor stress test induced changes on cardiovascular parameters and aortic wave reflections in healthy human subjects. This was a double-blind, placebo-controlled, crossover study. Participants were randomized to receive either two capsules of *P. emblica* extract 250

mg (containing aqueous extract of *P. emblica*, highly standardized by high-performance liquid chromatography to contain low molecular weight hydrolysable tannins emblicanin-A, emblicanin-B, pedunculagin and punigluconin) or two capsules of placebo twice daily for 14 days. Pharmacodynamic parameters such as heart rate, augmentation pressure, augmentation index (AIx), subendocardial viability ratio (SEVR), radial and aortic blood pressure (BP) were recorded before and after CPT at baseline and end of treatment. After washout period of 14 days, subjects crossed over to the other treatment and the same test procedure was repeated again. Safety assessments were done at baseline and at the end of treatment. Results: A total of 12volunteers completed the study. Compared with baseline and placebo, P. emblica extract produced a significant decrease of mean percent change in the indices of arterial stiffness (AIx, radial and aortic BP) and increase in SEVR, an index of myocardial perfusion with CPT. Both treatments were well-tolerated and no serious adverse events were reported. Proprietary *P. emblica* extract, showed a significant decrease in cold pressor stress test induced changes on aortic wave reflections.

76. Fatima, N., U. Pingali and N. Muralidhar (2014). "**Study of pharmacodynamic interaction of *Phyllanthus emblica* extract with clopidogrel and ecosprin in patients with type II diabetes mellitus.**" Phytomedicine **21**(5): 579-585.

Diabetes mellitus is associated with oxidative stress which impairs the platelet function. ***Phyllanthus emblica*** extract a rich source of vitamin C plays an important role in scavenging free radicals. The effect of vitamin C on platelet aggregation in healthy and coronary artery disease patients has been demonstrated. The present study attempts to study the pharmacodynamic interactions of *P. emblica* extract with clopidogrel and ecosprin. This was a randomized open label crossover study of 10 type II diabetic patients. The dosage schedules were either single dose of 500 mg *P. emblica* extract or 75 mg clopidogrel or 75 mg ecosprin or 500 mg P. emblica + 75 mg clopidogrel or 500 mg *P. emblica* + 75 mg ecosprin. After single dose study and washout period, patients received either 500 mg *P. emblica* extract twice daily or 75 mg clopidogrel or 75 mg ecosprin once daily or combinations for 10 days. Platelet aggregation was measured at baseline and at 4 h of treatment after single and multiple dose study along with recording of bleeding and clotting time. After single and multiple dose administration of the three treatments and with combinations there was statistically significant decrease of platelet aggregation compared to baseline. Further, the mean percent inhibition of platelet aggregation was significant, when compared between single and multiple doses of *P. emblica*. The bleeding and clotting time was prolonged with single and multiple dose administration of all treatments compared to baseline. All treatments were well tolerated. *P. emblica* extract demonstrated significant antiplatelet activity with both single and multiple dose administration.

77. Fischer-Rasmussen, W., S. K. Kjær, C. Dahl and U. Asping (1991). "**Ginger treatment of hyperemesis gravidarum.**" European Journal of Obstetrics and Gynecology and Reproductive Biology **38**(1): 19-24.

Thirty women participated in a double-blind randomized cross-over trial of the efficacy of a natural product, the powdered root of ginger (***Zingiber officinale***), and placebo in hyperemesis gravidarum. Three patients had to be withdrawn. Each

woman swallowed capsules containing either 250 mg ginger or lactose q.i.d. during the first 4 days of the treatment period. Interrupted by a 2 days wash-out period the alternative medication was given in the second 4-day period. The severity and relief of symptoms before and after each period were evaluated by two scoring systems. The scores were used for statistical analyses of possible differences. Subjectively assessed, 19 women (70.4%) stated preference to the period in which ginger, as was later disclosed, had been given (P = 0.003). More objectively assessed by relief scores a significantly greater relief of the symptoms was found after ginger treatment compared to placebo (P = 0.035). No side effects were observed. The possible mutagenic and antimutagenic characters of ginger reported in a study of E. coli have not been evaluated with respect to any significance in humans. Powdered root of ginger in daily doses of 1 g during 4 days was better than placebo in diminishing or eliminating the symptoms of hyperemesis gravidarum.

78. Fulzele, A. V., N. Ingle, M. N. Huda and D. S. Mishra (2014). "**Comparative study to evaluate the effect of a herbal preparation & shirodhara in the management of major depressive disorder.**" International Journal of PharmTech Research **6**(2): 506-511.

Depression is one of the most global public-health issues. In Ayurvedic Psychiatry, it is a complex disorder under the general category of Manas Roga. Patients usually show compliance with pharmacological antidepressant treatment which has many unpleasant side effects & it is quite expensive. With this issue, authors have undertaken this study to assess comparative effect of Herbal preparation & Shirodhara in management of major depressive disorder (MDD).Total 30 patients with mild and moderate type of major depressive disorder were included in a non-blind randomized controlled, open clinical study.The study population was collected from the OPD and IPD of Kayachikitsa at National Institute of Ayurveda and Hospital, Jaipur. Patients were divided into two groups named as Group A was given 5 gm herbal preparation t.d.s. p.o. for 42 consecutive days & Group B was given 5 gm herbal preparation t.d.s. p.o. for 42 consecutive days with Shirodhara therapy (oil dripping therapy) by medicated plain Ashwagandha oil for 14 consecutive days. Herbal preparation was made by the combination two indigenous medicinal plants, *Nardostachys jatamansi* and *Lavandula stoechas*. For the measurements of efficacy, the subjective parameters like clinical symptoms and objective parameters included HDRS-item 17, CGI-S were administered at baseline and the day of 42 and Clinical Global Improvement scales (CGI-I) was evaluated only the day of 42. End of treatment, the clinical symptoms and the HDRS 17, CGI-S and CGI-I score was found highly significant ($p<0.001$) improvement in both groups. So this study claimed that selected herbal preparation & Shirodhara both are effective and safe in mild and moderate condition of major depressive disorder.

79. Gajarmal, A. A. and M. B. Shende (2015). "**A clinical evaluation of antistress activity of Ashwagandha (*Withania somnifera* Dunal) on employees experiencing mental stress at work place.**" International Journal of Ayurveda and Pharma Research **3**(1): 37-45.

According to various surveys, the stress is the major problem for many diseases ranging from psychiatric disorders to endocrine disorders. In national capital regions like Mumbai, Chennai, Kolkata and Pune, as per the survey over 76% of senior and middle level executives working endure the highest levels of stress resulting into

mental and physical fatigue. Pertaining to the stress, modern medicine can provide some curable results but they are complicated and unsatisfactory. So the answer is hidden in Ayurveda i.e. Rasayana Chikitsa (Rejuvenation therapy). As similar to the modern concept of adaptogenic agents which gives the protection to the human physiological system against diverse stressor, recent studies shows that the Rasayana Dravyas having adaptogens which could induce a state of non-specific increase of resistance to affect internal homeostasis. The adaptogens improve the response to stress and help the body to adapt by normal physiological processes in times of increased stress. Therefore, Ashwagandha which is the best in Rasayana Karma, identified as ***Withania somnifera*** Dunal, is selected for the study. The present research work has been undertaken with the main objective as the clinical evaluation of antistress effect of Ashwagandha (*Withania somnifera* Dunal) on employees at different work places by various scientific parameters. In conclusion, Ashwagandha possesses potent anti-stress activity as it improves the mental faculties due to its psychotropic and tranquillizing effects over mind. Therefore, it can be used effectively in the management of stress.

80. Gannon, J. M., P. E. Forrest and K. N. R. Chengappa (2014). "**Subtle changes in thyroid indices during a placebo-controlled study of an extract of *Withania somnifera* in persons with bipolar disorder.**" Journal of Ayurveda and Integrative Medicine (J-AIM) **5**(4): 241-245.

Laboratory indices of thyroid function (TSH, Free T4, and T3) were measured in a randomized clinical trial in which Ashwagandha ***Withania somnifera*** (ASW) was used to improve cognitive function in patients with bipolar disorder. This was done in light of a case-report of ASW-associated thyrotoxicosis, and data from mice administered ASW that showed significant increases in thyroxine levels. Ten (of the original 60) patients showed abnormal results in one of the thyroid measures either at the beginning or end of the 8-week study. One ASW- treated patient had subclinical hypothyroidism (TSH - 5.7 mIU/L) at baseline that normalized, and all three ASW treated patients experienced T4 increases from baseline (7%, 12%, and 24%). Six of 7 placebo-assigned patients showed decreases in T4 from baseline (4% to 23%), and one patient's TSH moved from the normal to subclinical hypothyroid range (6.96 mIU/L). As thyroid indices were done for safety, and not the primary goal of the original study, only 16.7% had abnormal thyroid indices, and as there was no sub-stratification for treatment assignment by thyroid status, unequal numbers of subjects received ASW (n=3) or placebo (n=7). In spite of these limitations, the subtle laboratory changes noted in thyroid indices in an 8-week study suggest that ASW may increase thyroxine levels, and therefore vigilance regarding hyperthyroidism may be warranted. Nonetheless, the thyroid enhancing properties of ASW may also represent a clinical opportunity for the treatment of subclinical hypothyroidism, and these results suggest the need for further study of the effects of ASW on thyroid indices, especially in those with bipolar and unipolar mood disorders.

81. Garai, A. K., M. Rai and A. Kumar (2009). "**Role of an Ayurvedic compound (Panduhara Yoga) in the management of iron deficiency anaemia in children.**" AYU **30**(4): 469-474.

Pandu Roga (Anaemia) is one of the common problem in the developing countries like India specially in women and children. Iron deficiency anaemia (IDA) is the

commonest form of anaemia in children. Allopathic iron preparations are gastric irritant and having common side effects of oral iron including nausea, abdominal pain and either constipation or diarrhoea. To find out a satisfactory answer for the problem an Ayurvedic herbo-mineral compound (Mandura Bhasma one part +Amalaki Churna ten parts) was formulated and named as Panduhara Yoga. According to Ayurveda, Mandura Bhasma (ferrosoferic oxide) and Amalaki (***Emblica officinalis***) are very good drugs to prevent and manage the cases of Pandu Roga in children. Amalaki is Rasayana and it contains Vitamin-C that helps in the absorption of iron. Amalaki can increase bioavailability of Mandura Bhasma and can prevent the common hazards of oral iron therapy. A single blind clinical study was conducted in children of IDA. Panduhara Yoga has been administered in the dose of 110mg/kg body weight in two divided doses with honey after food for a period of 6 weeks. Hemoglobin level was improved with mean increase of 1.19gm/dl in three weeks (8.12g/dl to 9.31g/dl, $p<0.001$), and 2.64gm/dl in six weeks (8.12g/dl to 10.76/dl, $p<0.001$). After 6 weeks treatment with Panduhara Yoga overall 93.33% children showed very good improvement on clinical features, whereas 50% children showed very good improvement on blood hemoglobin level. The results suggest that Panduhara Yoga is significantly effective in the management of iron deficiency amaemia in children. No adverse effect has been noticed during the therapy.

82. Geeta, S., S. M. Kamath and R. P. Shenoy (2014). **Evaluating the usefulness and efficacy of the ayurvedic drug-*Tinospora cordifolia* in human.** In, South Regional Conference of the Association of Clinical Biochemists of India", 22-23 May 2014, Kasturba Medical College, Mangalore. Available at: http://eprints.manipal.edu/140092/.

Tinospora cordifolia (TC), known as "Guduchi"- an herbaceousvine of the family Menispermaceae indigenous to the tropical areas of India. The active principles of TC are found to possess immunomodulatory activities. There are a number of scientific and pre-clinical studies which have been done to evaluate the usefulness of this drug. The present study evaluates the multi-potent effect of TC as an effective drug for common acute conditions. 25 patients symptomatic with acute conditions like fever, cold, allergy & rhinitis reported at the Ayurveda Clinic of Kasturba Hospital, Manipal, Karnataka for the months July & August of 2011. These patients were administered TC extract in capsule form (from the Himalaya Drug Company) as 250 mg/ TD for 15 days. Before and after the administration of TC hematological testsand renal function tests were performed. No patient complained of any adverse/side effects during and after the period of the drug intake at the given dose and duration. A significant change was observed in Neutrophil, Eosinophil counts and ESR (p value < 0.05) after administration of TC. No changes observedin renal function tests.TC can be considered as an immunomodulatoryagent in cases of common acute conditions.In this study it was also observed that TC was effective in relieving the clinical symptoms that the patients reported prior to the administering of TC in cases of Allergic Rhinitis, Cold and fever and thereby boosting their immunity.

83. Geiger, J. L. (2005). "**The essential oil of ginger, *Zingiber officinale*, and anaesthesia.**" International Journal of Aromatherapy **15**(1): 7-14.

It is proposed that a 5% solution of essential oil of ginger, ***Zingiber officinale***, is an effective post-operative nausea and vomiting (PONV) prevention when administered

preoperatively, naso-cutaneously concurrently with conventional therapies to general anaesthesia patients at high risk for PONV. This is a summary of six months clinical experience and impressions of a single anaesthesia practitioner using best practice multimodal management plus 5% oil of ginger, *Zingiber officinale*, in the prevention of PONV in high risk group adult patients. The results of the clinical experience show improvement gained in patient response as measured by lower incidence of nausea and vomiting in the post-anaesthesia recovery unit (PACU). The group treated with the essential oil of ginger experienced approximately less than 20% nausea in the PACU. This low percentage of high risk PONV patients that experienced nausea in the ginger group mostly required only one single intravenous supplemental medication to control nausea. Approximately, 80% of high risk patients had no complaint of PONV and therefore did not require any further intravenous therapy during recovery from anaesthesia through discharge from PACU. The non-ginger oil treated patients in this clinical experience had a roughly 50/50 chance of PONV. A 5% solution of the essential oil of *Zingiber officinale* in grape seed carrier oil, when applied naso-cutaneously, can be administered safely for the effective prevention and therapeutic management of nausea in general anaesthesia patients at high risk for post-operative nausea and vomiting, with increased patient satisfaction and less expense to patients and hospital. Guidelines and regulations established for the safe use of integrative therapy with an essential oil are critical to observe.

84. Ghiware, N., T. Nesari and N. Gond (2007). "**Clinical validation of *Piper nigrum* and *Nyctanthes arbor-tristis* formulation for antimalarial activity.**" J Res Educ Indian Med **13**: 33-38.

An uncontrolled, open label clinical study was done on twenty-one smear positive patients of Plasmodium vivax malaria. High solid content deflocculated suspension of ***Piper nigrum*** and Nyctanthes arbortristis was given to patients after their enrollment in study. Vital signs and symptoms of malaria as body temperature, chilly felling/rigors, headache, body ache, nausea/vomiting and anemia were recorded before treatment, after first and second week of treatment. Improvement in condition was recorded as shifting of gradation in signs of malaria. Decrease in increased body temperature was recorded at the end of first week of treatment ($P<0.001$). Global assessment suggests improvement within first week of treatment from chilly felling/rigors, headache and body ache. Recovery from nausea/vomiting and anemic signs was observed only after second week of treatment. Negative smear test for Plasmodium vivax was observed at the end of treatment schedule in all patients.

85. Giacosa, A., D. Guido, M. Grassi, A. Riva, P. Morazzoni, E. Bombardelli, S. Perna, M. A. Faliva and M. Rondanelli (2015). "**The effect of ginger (*Zingiber officinalis*) and artichoke (*Cynara cardunculus*) extract supplementation on functional dyspepsia: A randomised, double-blind, and placebo-controlled clinical trial.**" Evidence-based Complementary and Alternative Medicine **2015**. Article number 915087.

Functional dyspepsia (FD) is a frequent clinical finding in western world. The aim of this study is to compare the efficacy of a ginger (***Zingiber officinale***) and artichoke supplementation versus placebo in the treatment of FD. A prospective multicentre, double blind, randomized, placebo controlled, parallel-group comparison of the supplement and placebo over a period of 4 weeks was performed. Two capsules/day

were supplied (before lunch and dinner) to 126 FD patients (supplementation/placebo: 65/61). After 14 days of treatment, only supplementation group (SG) showed a significant amelioration (SG: αS=+1.195 MCA score units (u), P=0.017; placebo: αP=+0.347 u, P=0.513). The intercept (α) resulted to be significantly higher in SG than in placebo (αS-αP=+0.848 u, P<0.001). At the end of the study, the advantage of SG versus placebo persists without variation (βS-βP=+0.077 u, P=0.542). In SG, a significant advantage is observed for nausea (βS-βP=-0.398 u, P<0.001), epigastric fullness (βS-βP=-0.241, P<0.001), epigastric pain (βS-βP=-0.173 u, P=0.002), and bloating (βS-βP=-0.167 u, P=0.017). The association between ginger and artichoke leaf extracts appears safe and efficacious in the treatment of FD and could represent a promising treatment for this disease.

86. Gohel, S. D., I. Anand and K. Patel (2011). "**A comparative study on efficacy of Bharangyadi Avaleha and Vasa Avaleha in the management of Tamaka Shwasa with reference to childhood asthma.**" AYU **32**(1): 82-89.

Ayurvedic concept is of the opinion that Tamaka Shwasa (Bronchial Asthma) is a Yapya Vyadhi. The etiopathogenesis, signs, and symptoms of Tamaka Shwasa may be correlated with Bronchial Asthma. Each child reacts differently to the factors that trigger asthma and treated symptomatically. Asthma is the most common chronic allergic disorder in childhood and third leading cause of hospitalization under the age of 15 years. As it is a Kapha-Vata predominant disorder, Ayurvedic medicine may help to decrease the recurrence, improve immunity, and check symptoms naturally. With this aim, a clinical study was undertaken on two groups for duration of 6 weeks. The drugs Bharangyadi Avaleha and Vasa Avaleha were given orally, separately in both the groups. Bharangyadi Avaleha contains Bharangi (*Clerodendrum serratum* Linn), Kasamarda (*Cassia occidentalis* Linn.), Vasa (*Adhatoda vasica* Nees.), Maricha (***Piper nigrum*** Linn.), Pippali (***Piper longum*** Linn.), Haridra (*Curcuma longa* Linn.), Guduchi (***Tinospora cordifolia*** Miers.), Sunthi (***Zingiber officinale*** Roscoe.), Dhanyaka (*Coriandrum sativum* Linn.), Madhu, Mishri and Ghrita. Contents of Vasa Avaleha are Vasa (*Adhatoda vasica* Nees.), Pippali (*Piper longum* Linn) and Madhu, Mishri and Ghrita. All the patients were kept under strict dietary control during the treatment. The observation on effect of therapy was encouraging and showed less recurrence.

87. Gopa, B., J. Bhatt and K. G. Hemavathi (2012). "**A comparative clinical study of hypolipidemic efficacy of Amla (*Emblica officinalis*) with 3-hydroxy-3-methylglutaryl-coenzyme-A reductase inhibitor simvastatin.**" Indian Journal of Pharmacology **44**(2): 238-242.

To evaluate the efficacy of Amla (***Emblica officinalis***) in patients with type II hyperlipidemia and compare its hypolipidemic effects with those of simvastatin. Sixty type II hyperlipidemic patients of both sexes with plasma total cholesterol and low density lipoprotein level more than 240 mg% and 130 mg%, respectively, were selected for the trial. Out of total 60 selected patients, 40 were treated with Amla capsule (500 mg) daily for 42 days and 20 patients were given simvastatin capsule (20 mg) daily for 42 days. After the day of enrolment, all patients were followed up twice during the 42-day period. Blood samples were analyzed for various biochemical parameters and the values of Total Cholesterol (TC), Low Density Lipoprotein (LDL),

High Density Lipoprotein (HDL), and Very Low Density Lipoprotein (VLDL) were measured before and after completion of the treatment with Amla and simvastatin. Cardiovascular parameters were recorded before and after completion of treatment. Results: Treatment with Amla produced significant reduction of TC ($P<0.0001$), LDL ($P<0.0001$), triglyceride (TG) and VLDL ($P<0.0002$), and a significant increase in HDL levels ($P<0.0002$). Similarly, treatment with simvastatin produced significant reduction of TC ($P<0.0001$), LDL ($P<0.0009$), TG and VLDL ($P<0.017$), and a significant increase in HDL levels ($P<0.0001$). Both treatments produced significant reduction in blood pressure; however, this beneficial effect was more marked in patients receiving Amla. In view of the above findings, it is suggested that Amla produced significant hypolipidemic effect along with a reduction in blood pressure. Addition of Amla to the currently available hypolipidemic therapy would offer significant protection against atherosclerosis and coronary artery disease, with reduction in the dose and adverse effects of the hypolipidemic agents.

88. Grøntved, A. and E. Hentzer (1986). "**Vertigo-reducing effect of ginger root: A controlled clinical study.**" ORL **48**(5): 282-286.

The effect of powdered ginger root (***Zingiber officinale***) upon vertigo and nystagmus following caloric stimulation of the vestibular system was studied in 8 healthy volunteers in a double-blind crossover placebo trial. The results reported are based upon 48 vertigo scores and 48 electronystagmograms. Ginger root reduced the induced vertigo significantly better than did placebo. There was no statistically significant action upon the duration or the maximum slow phase velocity of nystagmus.

89. Grøntved, A., T. Brask, J. Kambskard and E. Hentzer (1988). "**Ginger root against seasickness: A conctrolled trial on the open sea.**" Acta Oto-Laryngologica **105**(1-2): 45-49.

In a double-blind randomized placebo trial, the effect of the powdered rhizome of ginger (***Zingiber officinale***) was tested on seasickness. Eighty naval cadets, unaccustomed to sailing in heavy seas reported during voyages on the high seas, symptoms of seasickness every hour for 4 consecutive hours after ingestion of 1 g of the drug or placebo. Ginger root reduced the tendency to vomiting and cold sweating significantly better than placebo did ($p<0.05$). With regard to vomiting, a modified Protection Index (PI)=72% was calculated. Remarkably fewer symptoms of nausea and vertigo were reported after ginger root ingestion, but the difference was not statistically significant. For all symptom categories, PI=38% was calculated.

90. Guo, R., M. H. Pittler and E. Ernst (2007). "**Herbal medicines for the treatment of allergic rhinitis: A systematic review.**" Annals of Allergy, Asthma and Immunology **99**(6): 483-495.

Study evaluated the efficacy of herbal medicines for the treatment of allergic rhinitis (AR) using five electronic databases until November 8, 2005; bibliographies of located articles; manufacturers of commercially available preparations; and experts in the field. Authors only included double-blind randomized clinical trials (RCTs), which tested a herbal medicine against placebo or active comparator, in patients with AR, and evaluated clinically relevant outcomes. Study selection, data extraction, and evaluation of methodological quality were performed independently by 2 reviewers.

Discrepancies were resolved by discussion and by seeking the opinion of the third reviewer. Meta-analysis was only performed if data were considered suitable for pooling. Sixteen eligible RCTs, testing 10 different herbal products against placebo or active comparator, were included. Six RCTs studied Petasites hybridus (butterbur) extract for AR and suggest that P hybridus is superior to placebo or similarly effective compared with nonsedative antihistamines for intermittent AR. Two RCTs studied an Indian herbal combination, Aller-7, in patients with AR and reported positive results. Single RCTs were identified for 8 other herbal products as treatments for AR, reporting positive outcomes, except for grape seed extract. The median methodological quality score was 4 of a possible maximum of 5. There is encouraging evidence suggesting that P hybridus may be an effective herbal treatment for seasonal (intermittent) AR. However, independent replication is required before a firm conclusion can be drawn because of the financial support from the manufacturer of P hybridus extract to the 3 large trials. There are also promising results generated for other herbal products, particularly Aller-7, ***Tinospora cordifolia***, *Perilla frutescens*, and several Chinese herbal medicines. Although these results are confined to the paucity of data and the small sample size, confirmation in larger and more rigorously designed clinical trials is warranted.

91. Gupta, A., A. A. Mahdi, K. K. Shukla, M. K. Ahmad, N. Bansal, P. Sankhwar and S. N. Sankhwar (2013). "**Efficacy of *Withania somnifera* on seminal plasma metabolites of infertile males: A proton NMR study at 800 MHz.**" Journal of Ethnopharmacology **149**(1): 208-214.

Ethnopharmacological relevance Traditional Indian systems of medicine use roots of ***Withania somnifera*** for impotence, infertility treatment, stress, and the aging process. Although *Withania somnifera* improves semen quality by regulating reproductive hormone levels and oxidative stress, the molecular mechanism is not clear. Aim of the study This study uses high-resolution Nuclear Magnetic Resonance (NMR) spectroscopy to explore the scientific basis to reveal the pre- and post-treatment efficacy of *Withania somnifera* on seminal plasma of infertile men - which remains unexplored to date. Materials and methods A total of 180 infertile male patients were administered *Withania somnifera* root powder at the rate of 5 g/d for a 3-month period. The study included age-matched, healthy men as a control (n=50) group. Proton NMR spectroscopy was used to measure lactate, alanine, glutamate, glutamine, citrate, lysine, choline, glycerophosphocholine (GPC), glycine, tyrosine, histidine, phenylalanine, and uridine in all seminal plasma samples. To appraise infertility levels, authors also measured sperm concentration, motility, lipid peroxide, and hormonal perturbation. Results *Withania somnifera* therapy repairs the disturbed concentrations of lactate, alanine, citrate, GPC, histidine, and phenylalanine in seminal plasma and recovers the quality of semen of post-treated compared to pre-treated infertile men. Serum biochemistry was also improved over post-therapy in infertile men. Findings reveal that *Withania somnifera* not only reboots enzymatic activity of metabolic pathways and energy metabolism but also invigorates the harmonic balance of seminal plasma metabolites and reproductive hormones in infertile men. The results suggest that *Withania somnifera* may be used as an empirical therapy for clinical management and treatment of infertility.

92. Gupta, A. K., K. Acharya, P. S. Sancheti and R. S. Joshi (2011). "**A double-blind, randomized, multicentric, placebo-controlled clinical trial of antarth, a phytomedicine, in the treatment of osteoarthritis.**" Indian Journal of Pharmacology **43**(1): 69-72.

Objective was to test Antarth, (a polyherbal phytomedicine containing *Boswellia serrata, Commiphora mukul, Curcuma longa, Vitex negundo, Alpinia galangal,* ***Withania somnifera****, Tribulus terrestris, and* ***Tinospora cordifolia***), for its efficacy and safety in patients with osteoarthritis (OA) and compared with placebo. A total of 90 male or female adult patients who were diagnosed clinically and radiologically with OA were recruited in the study. Antarth or placebo was given 2 capsules b.i.d. for 3 months and the patients were assessed every month for its efficacy. Diclofenac sodium was allowed to be taken as rescue medication. After 3 months of treatment, the reduction in severity of pain on Visual Analog Scale (VAS) was more in Antarth group compared to placebo but the difference between the two groups was not significant. However, pain during functioning of disabled joints while walking distance, squatting, sitting cross-legged and climbing steps were significantly reduced in Antarth group compared to placebo ($P < 0.05$). Reduction in consumption of rescue medication, diclofenac sodium, was more in Antarth than in placebo group. In Patients' Global Assessment, patients treated with Antarth were more satisfied than the ones treated with placebo. Observations were similar in Physicians' Global Assessment too. There were no adverse events in both the groups.

93. Gupta, D., D. J. Bhaskar, R. K. Gupta, B. Karim, V. Gupta, H. Punia, M. Batra, A. Jain, A. Agarwal and P. Singh (2014). "**Effect of *Terminalia chebula* extract and chlorhexidine on salivary pH and periodontal health: 2 weeks randomized control trial.**" Phytotherapy Research **28**(7): 992-998.

A double blind, randomized, controlled study with three parallel treatment groups was done to evaluate the efficacy of a ***Terminalia chebula*** 10% mouth rinse compared with chlorhexidine 0.12% mouth rinse, applied two times daily for 2 weeks, in the treatment of dental plaque and gingivitis. Seventy-eight patients were included in the study. The efficacy variables were periodontal indices on days 0, 7 and 14 after commencement of therapy. Twenty six patients received chlorhexidine mouth rinse, twenty six *Terminalia chebula* mouth rinse and twenty six received saline solution. The clinical parameters were significantly reduced by both chlorhexidine and *Terminalia chebula* mouth rinse although no significant difference was seen between the two groups ($P>0.05$). This study demonstrated that *Terminalia chebula* mouth rinse is effective in reducing microbial plaque, gingival inflammation and neutralizing salivary pH.

94. Gupta, D., R. K. Gupta, D. J. Bhaskar and V. Gupta (2015). "**Comparative evaluation of *Terminalia chebula* extract mouthwash and chlorhexidine mouthwash on plaque and gingival inflammation - 4-week randomised control trial.**" Oral health & preventive dentistry **13**(1): 5-12.

The present study was conducted to assess the effectiveness of ***Terminalia chebula*** on plaque and gingival inflammation and compare it with the gold standard chlorhexidine (CHX 0.2%) and distilled water as control (placebo). A double-blind randomised control trial was conducted among undergraduate students who volunteered. They were randomly allocated into three study groups: 1) *Terminalia*

chebula mouthwash (n = 30); 2) chlorhexidine (active control) (n = 30); 3) distilled water (placebo) (n = 30). Assessment was carried out according to plaque score and gingival score. Statistical analysis was carried out to compare the effect of both mouthwashes. ANOVA and post-hoc LSD tests were performed using SPSS version 17 with $p \leq 0.05$ considered statistically significant. These result showed that *Terminalia chebula* mouthrinse is as effective as chlorhexidine in reducing dental plaque and gingival inflammation. The results demonstrated a significant reduction of gingival bleeding and plaque indices in both groups over a period of 15 and 30 days as compared to the placebo. *Terminalia chebula* extract mouthrinse can be used as an alternative to chlorhexidine mouthrinse as it has similar properties without the side-effects of the latter.

95. Gupta, K., P. Mamidi and A. B. Thakar (2014). "**Randomised placebo controlled study on Sarasvata choorna in generalised anxiety disorder.**" International Journal of Green Pharmacy **8**(4): 231-236.

Generalised anxiety disorder (GAD) is characterised by a pattern of frequent, persistent worry and anxiety, which is out of proportion to the impact of the event or circumstance that is the focus of the worry. GAD is associated with muscle tension, trembling, twitching, feeling shaky and muscle aches or soreness. Many individuals with GAD also experience somatic symptoms like sweating, nausea and diarrhoea. Epidemiological studies reveal that the prevalence rate of GAD in India is 5.8%. The main objective of the present study was to evaluate the efficacy of Sarasvata choorna in the management of GAD. Sarasvata choorna contains various ingredients that have different properties such as anxiolytic (vacha, brahmi, shankhapushpi, ashwagandha), anti-depressant (shankhapushpi, ashwagandha (***Withania somnifera***), vacha, brahmi, sunthi [***Zingiber officinale*** Roscoe]), muscle relaxant (patha [Cissampelos pareira L], brahmi), tranquiliser or sedative (vacha, ashwagandha) anti-stress and adaptogen (ashwagandha, shankhapushpi, brahmi, etc.) deepana and paachana (sunthi, pippali [***Piper longum*** L], maricha [***Piper nigrum*** L], ajamoda [*Apium graveolens* S], saindhava lavana [Rock salt], krishna jeeraka [*Carum carvi* L], sweta jeeraka [*Cuminum cyminum* L], etc.), analgesic (ajamoda, ashwagandha, sunthi, maricha, etc.), rasayana and medhya rasayana (brahmi, shankhapushpi, vacha, ashwagandha, kushta, etc.), unmadahara (vacha, brahmi, kushta, shankhapushpi, etc.). In this study, a total of 114 patients with GAD satisfying the Diagnostic and Statistical Manual of Mental Disorders - Text Revision (DSM IV - TR) diagnostic criteria were selected and randomly divided; of these, 102 patients completed the course of treatment. In trial group, Sarasvata choorna and in control group, placebo (wheat powder) was given with the dose of 1 g thrice a day (i.e. 3 g/day) along with madhu (honey) and ghrita (cow's ghee) orally for 60 days. Fifteen days of follow up period was kept after treatment. Two assessments were done before and after treatment. Criterion of assessment was based on the scoring of Hamilton Anxiety Rating Scale (HAM-A). Paired and unpaired 't'- test was used for statistical analysis. In trial group (n = 51), 51.1% improvement and in control group (n = 51), 47.67% of improvement was observed with the significance of ($P < 0.001$). No statistically significant difference ($P > 0.05$) was found in between the two groups. Sarasvata choorna did not provide better relief compared with placebo. [Note from the editors: This research did not clearly note if the drug quality was tested before trial].

96. Gupta, M., B. P. Shaw and A. Mukherjee (2008). "**Evaluation of antipyretic effect of a traditional polyherbal preparation: A double-blind, randomized clinical trial.**" International Journal of Pharmacology **4**(3): 190-195.

The ancient Ayurvedic text Charak samhita of Indian medicine prescribes a specific group of ten plants having antipyretic properties with minimal side-effects. The aqueous extract of polyherbal ayurvedic preparation PD-10 (from the roots of *Hemidesmus indicus* R. Br. (Asclepiadaceae), *Rubia cordifolia* L. (Rubiaceac), *Cissampelos pareira* L. (Menispermaceae), fruits of ***Terminalia chebula*** Retz. (Combretaceae), ***Emblica officinalis*** Gaertn. (Euphorbiaceae), ***Terminalia bellirica*** Roxb. (Combretaceae), *Vitis vinifera* L. (Vitaceae), *Grewia asiatica* L. (Tillaceae), *Salvadora persica* L. (Salvadoraceae) and granules of *Saccharum officinarum* L. (Poaceae)) exhibited significant antipyretic-analgesic properties during rodent experiments while exhibiting low toxicity and ulcerogenicity. The presence of flavonoids, tannins and polyphenols in this extract prompted this double-blind, randomized clinical trial on 60 patients using Aspirinv (60 mg kg-1 body weight per day) as the standard drug for comparison. The primary outcome measured was reduction in body temperature, while the secondary outcomes measured were prevalence of associated symptoms of fever and routine blood and urine parameters. A representative sample of patients was also studied for reduction in the level of Prostaglandin (PGE2). The clinical trial showed that fever was rapidly and substantially reduced after oral administration of PD-10 and this antipyretic effect was more sustained and highly significant when compared to Aspirin. Many associated symptoms of fever also exhibited significant reductions when PD-10 was administered as compared to Aspirin. Prostaglandin levels also registered a substantial decrease during treatment with the test drug.

97. Haghighi, M., A. Khalvat, T. Toliat and S. Jallaei (2005). "**Comparing the effects of ginger (*Zingiber officinale*) extract and ibuprofen on patients with osteoarthritis.**" Archives of Iranian Medicine **8**(4): 267-271.

Ginger (***Zingiber officinale***) extract supplementation has been shown to improve the severity of symptoms and decrease the nonsteroidal antiinflammatory drug (NSAID) requirements in patients with osteoarthritis (OA). To assess the effects of ginger extract as an alternative to NSAIDs and as a supplement drug in the symptomatic treatment of OA. Methods: Between April and October 2002, 120 outpatients with OA of moderate to severe pain, requiring only the use of NSAIDs, were enrolled into a double-blind, randomized, placebo-controlled clinical trial. These patients were randomized into three groups of 40, including the placebo (PL), ginger extract (GE), and ibuprofen (IBP) groups. After a washout period of one week (week 0), patients received either 30 mg ginger extract in two 500 mg capsules, placebo, or three 400 mg ibuprofen tablets daily for one month. Acetaminophen tablet was prescribed as a rescue analgesic during the study. The clinical assessments included a visual analog scale (VAS) for pain, gelling pain, joint swelling measurement, and joint motion slope measurement. Joint motion slope was measured by goniometry (normal = 130°, limited = 120°, and very limited = 110°). Results: The improvement of symptoms (defined as reduction in the mean change) was superior in the ginger extract and ibuprofen groups than the placebo group. VAS scores and gelling or regressive pain

after rising the scores were significantly higher in the PL group than both the GE and IBP groups, a month after the treatment ($P < 0.0001$). However, there was no significant difference in VAS and gelling pain scores between the ginger extract and the ibuprofen groups. Ginger extract and ibuprofen were significantly more effective than the placebo in the symptomatic treatment of OA, while there was no significant difference between the ginger extract and ibuprofen groups in a test for multiple comparison.

98. Hasani-Ranjbar, S., N. Nayebi, L. Moradi, A. Mehri, B. Larijani and M. Abdollahi (2010). "**The efficacy and safety of herbal medicines used in the treatment of hyperlipidemia; a systematic review.**" Current Pharmaceutical Design **16**(26): 2935-2947.

This review focuses on the efficacy and safety of effective herbal medicines in the management of hyperlipidemia in human. PubMed, Scopus, Google Scholar, Web of Science, and IranMedex databases were searched up to 11th May 2010. The search terms were "hyperlipidemia" and ("herbal medicine" or "medicine traditional", "extract plant") without narrowing or limiting search elements. All of the human studies on the effects of herbs with the key outcome of change in lipid profiles were included. Fifty three relevant clinical trials were reviewed for efficacy of plants. This study showed significant decrease in total cholesterol and LDL cholesterol after treatment with Daming capsule (DMC), chunghyul-dan, Glycyrrhiza glabra, garlic powder (Allicor), black tea, green tea, soy drink enriched with plant sterols, licorice, Satureja khuzestanica, Monascus purpureus Went rice, Fenugreek, Commiphora mukul (guggul), Achillea wilhelmsii C. Koch, Ningzhi capsule (NZC), cherry, compositie salviae dropping pill (CSDP), shanzha xiaozhi capsule, Ba-wei-wan (hachimijiogan), rhubarb stalk, Silybum marianum, Rheum Ribes and Jingmingdan granule (primrose oil). Conflicting data exist for red yeast rice, garlic and guggul. No significant adverse effect or mortality were observed except in studies with DMC, guggul, and ***Terminalia bellirica***, ***Terminalia chebula***, ***Emblica officinalis***, ginger (***Zinziber officinale***), and garlic powder (Allium sativum). Amongst reviewed studies, 22 natural products were found effective in the treatment of hyperlipidemia that deserve further works to isolate and characterization of their constituents to reach novel therapeutic and more effective agents.

99. Hickok, J. T., J. A. Roscoe, G. R. Morrow and J. L. Ryan (2007). "**A phase II/III randomized, placebo-controlled, double-blind clinical trial of ginger (*Zingiber officinale*) for nausea caused by chemotherapy for cancer: A currently accruing URCC CCOP Cancer Control study.**" Supportive Cancer Therapy **4**(4): 247-250.

Despite the widespread use of 5-HT3 receptor antagonist antiemetics such as ondansetron and granistron, up to 70% of patients with cancer receiving highly emetogenic chemotherapy agents experience postchemotherapy nausea and vomiting. Delayed postchemotherapy nausea (nausea that occurs ≥ 24 hours after chemotherapy administration) and anticipatory nausea (nausea that develops before chemotherapy administration, in anticipation of it) are poorly controlled by currently available antiemetic agents. Scientific studies suggest that ginger (***Zingiber officinale***) might have beneficial effects on nausea and vomiting associated with motion sickness, surgery, and pregnancy. In 2 small studies of patients with cancer receiving chemotherapy, addition of ginger to standard antiemetic medication further

reduced the severity of postchemotherapy nausea. This article describes a phase II/III randomized, dose-finding, placebo-controlled, double-blind clinical trial to assess the efficacy of ginger for nausea associated with chemotherapy for cancer. The study is currently being conducted by private practice oncology groups that are funded by the National Cancer Institute's Community Clinical Oncology Program and affiliated with the University of Rochester Cancer Center Community Clinical Oncology Program Research Base.

100. Hsia, S. H., M. Bazargan and M. B. Davidson (2004). "**Effect of pancreas tonic (an Ayurvedic herbal supplement) in type 2 diabetes mellitus.**" Metabolism: Clinical and Experimental **53**(9): 1166-1173.

Although there is widespread use of herbal dietary supplements that are believed to benefit type 2 diabetes mellitus, few have been proven to do so in properly designed randomized trials; their efficacy for intermediate-term glucose control remains unclear. Pancreas Tonic is a botanical mixture of traditional Indian Ayurvedic herbs currently available as a dietary supplement. Authors report the results of a single-center, randomized, double-blind, placebo-controlled 3-month trial of Pancreas Tonic in type 2 diabetic patients inadequately treated with diet/lifestyle or stable doses of sulfonylureas and/or metformin for at least 3 months. Patients with type 2 diabetes for ≥ 1 year were entered into 2 strata of hemoglobin A 1c (HbA 1c) levels (stratum 1: 8.0% to 9.9%; stratum 2: 10.0% to 12.0%). Composition of toin includes *Aegle marmelose, Pterocarpus marsupium, Syzigium cumini, Momordica charantia, Gymnema sylvestre, Trigonella foenum graecum, Azadirachta indica, Ficus racemosa,* ***Tinospora cordifolia****, Cinnamomum tamala*. All subjects began a 1-month single-blind placebo run-in phase, followed by randomization in a 2:1 ratio of active treatment: placebo, to 3 months of double-blind treatment with either Pancreas Tonic or matching placebo (2 capsules 3 times a day). Concurrent oral agents were continued unchanged throughout the study. The primary outcome was the change in HbA 1c from randomization; results of each stratum were analyzed independently. The baseline characteristics of 36 subjects who completed the study were comparable between treatment groups. Nineteen subjects entered stratum 1 and 17 entered stratum 2. A statistically significant reduction of HbA 1c from randomization to end-of-study was seen in the stratum 2 subjects (Pancreas Tonic: 10.1% ± 1.0% to 8.8% ± 1.9%, P = .004; placebo: 10.8% ± 1.4% to 11.2% ± 1.8%, not significant [NS]). No significant HbA 1c reductions were seen in the stratum 1 subjects. There were no significant treatment-related differences in the fasting plasma glucose (FPG), lipids, body mass index (BMI), body composition, blood pressure, insulin sensitivity estimates using the minimal model, glucose and insulin responses to a meal challenge, quality of life, adverse events, or other safety indices between treatment groups. Pancreas Tonic was well tolerated. Treatment with Pancreas Tonic (2 capsules 3 times per day) for 3 months significantly improved glucose control in type 2 diabetic patients with HbA 1c levels between 10.0% to 12.0%. This study represents the first properly designed, prospective intervention trial of therapy with an Ayurvedic herbal supplement for intermediate-term glucose control in type 2 diabetes.

101. Huda, N. M., D. S. Mishra and J. Singh (2015). "**Clinical evaluation of an Ayurvedic preparation or the treatment of iron deficiency anemia in patients.**" Journal of Homeopathy & Ayurvedic Medicine **3**: doi: 10.4172/2167-1206.1000162.

Iron deficiency anemia is the most widespread nutritional disorder in the world. Prevalence of anaemia in Indian subcontinent is high because of low dietary intake, poor availability of iron and chronic blood loss due to hook worm infestation and malaria. Numbers of preparations are available in Ayurveda for correction of Iron deficiency anemia. So this study was conducted to investigate the efficacy of two Ayurvedic formulations Dhatri louha and Novayas louha in anaemic patients. It was a randomized, non-blinded, and placebo controlled pre-posttest design. Total thirty patients were divided into three groups. Each group contained 10 numbers of patients. Group 1 (control group) was given one starch capsule daily for 30 days and Group 2 and Group 3 were given two Ayurvedic formulations Dhatri louha and Novayas louha respectively in a dose of 250 mg twice a day for 30 days. Hematological parameters like hemoglobin concentration, packed cell volume, mean corpuscular volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration were determined before and after completion of treatment. After the 30 days of treatment it was found significant ($p<0.05$) response in Group 2 and Group 3 when compared with Group 1. Therefore, it claimed that Dhatri louha and Novayas louha have haemopoetic function although it was a preliminary work. Dhatri Lauha contains ***Emblica officinalis***, ***Terminalia chebula***, ***Terminalia bellirica***, ***Zingiber officinale***, ***Piper longum***, ***Piper nigrum***, *Plumbago zeylanica*, *Cyperus rotundus*, *Emblica ribes* and Louha bashma.

102. Huded, S., S. V. Gummadi, K. Sankh, H. N. Asha, H. S. Ashwini and K. Lingadore (2013). "**Evaluation of guduchi yoga in the management of vatarakta (gouty arthritis): A clinical study.**" International Journal of Research in Ayurveda and Pharmacy **4**(5): 688-692.

Vatarakta is one of the main articular diseases, which is characterized by severe pain, tenderness, inflammation and burning sensation in the affected joints. It is a tridoshaja vyadhi, with vata pradhanyata and rakta as main dushya. Sedentary lifestyle is one of the etiological factors of Vatarakta. The etiology and symptomatology of Gout is very much similar to that of Vatarakta. Gout is a pathological reaction of joint or periarticular tissues which results from deposition of monosodium urate monohydrate crystals in joints and tissues. In Ayurvedic classics, although there are many dravyas for joint disorders, the area of joint diseases management still remains to be elusive. Hence the present clinical study aims to evaluate the efficacy of combined effect of 'Guduchi extract (***Tinospora cordifolia***) and cucumber juice extract' in the management of Vatarakta (Gouty arthritis). In the present study, 20 patients fulfilling the diagnostic criteria of Vatarakta and who met the American College of Rheumatology (ACR) criteria for acute Gouty arthritis were selected. Detailed profile which incorporated relevant data like symptomatology, physical signs and investigation reports were considered for assessment criteria. The 'Guduchi Yoga' (Aqueous extract of Guduchi and Trapusha) was administered to patients of either sex in the dosage of 1 g BID with lukewarm water after food for 12 weeks (3 months). After the course of therapy for 12 weeks, symptomatic improvement was observed with statistically significant results ($P < 0.001$) along with attainment of normal serum uric acid levels followed by feeling of general wellbeing. From the present study it can

be concluded that the combined effect of Guduchi and Trapusha extracts showed promising results in the management of vatarakta.

103. Imani, H., H. Tabibi, I. Najafi, S. Atabak, M. Hedayati and L. Rahmani (2015). "**Effects of ginger on serum glucose, advanced glycation end products, and inflammation in peritoneal dialysis patients.**" Nutrition **31**(5): 703-707.

The aim of this study was to investigate the effects of ginger (***Zingiber officinale***) supplementation on serum glucose, advanced glycation end products, oxidative stress, and systemic and vascular inflammatory markers in patients on peritoneal dialysis (PD). In this randomized, double-blind, placebo-controlled trial, 36 patients on PD were randomly assigned to either the ginger or the placebo group. The patients in the ginger group received 1000mg/d ginger for 10wk, whereas the placebo group received corresponding placebos. At baseline and the end of week 10, serum concentrations of glucose, carboxymethyl lysine, pentosidine, malondialdehyde (MDA), high-sensitivity C-reactive protein (hs-CRP), soluble intercellular adhesion molecule type 1 (sICAM-1), soluble vascular cell adhesion molecule type 1 (sVCAM-1), and sE-selectin were measured after a 12- to 14-h fast. Results: Serum fasting glucose decreased significantly up to 20% in the ginger group at the end of week 10 compared with baseline ($P<0.05$), and the reduction was significant in comparison with the placebo group ($P<0.05$). There were no significant differences between the two groups in mean changes of serum carboxymethyl lysine, pentosidine, MDA, hs-CRP, sICAM-1, sVCAM-1, and sE-selectin. This study indicated that daily administration of 1000mg ginger reduces serum fasting glucose, which is a risk factor for hyperinsulinemia, dyslipidemia, peritoneal membrane fibrosis, and cardiovascular disease, in patients on PD.

104. Jacob, A., M. Pandey, S. Kapoor and R. Saroja (1988). "**Effect of the Indian gooseberry (amla) on serum cholesterol levels in men aged 35-55 years.**" European Journal of Clinical Nutrition **42**(11): 939-944.

The effect on total serum cholesterol and its lipoprotein fractions of supplementation of the diet with amla (***Emblica officinalis***, Gaertn., the Indian gooseberry) was studied in normal and hypercholesterolaemic men aged 35-55 years. The supplement was given for a period of 28 d in the raw form. Both normal and hypercholesterolaemic subjects showed a decrease in cholesterol levels. **Two weeks after withdrawing the supplement, the total serum cholesterol levels of the hypercholesterolaemic subjects rose significantly almost to initial levels**.

105. Jain, C. (2008). "**Clinical Study of Immunomodulatory Effect of an Ayurvedic Compound (Vayasthadi Yoga) in Children.**" AYU (An international quarterly journal of research in Ayurveda) **29**(3): 123-127.

The immune system plays a vital role in maintaining the body's overall health and resistance to disease. In children, the immune system is in immature state and thus, they are unable to protect the body from invaders. They are suffered from recurrent infections. These infections are suggestive of a deficiency in the local or systemic host defence. In this clinical study, an Ayurvedic compound "Vayasthadi Yoga" containing Haritaki (***Terminalia chebula***), Pippali (***Piper longum***), Kustha, Haridra, Sariva, Vacha, Jatamansi, Kaidarya Brahmihas, shown statistically significant improvement in

morbidity features - Running nose, Sore throat, Nasal obstruction, Enlarged tonsils, Cough, Dyspnoea, Fever and Diarrhoea.

106. Janssen, P. L. T. M. K., S. Meyboom, W. A. Van Staveren, F. De Vegt and M. B. Katan (1996). "**Consumption of ginger (*Zingiber officinale* Roscoe) does not affect ex vivo platelet thromboxane production in humans.**" European Journal of Clinical Nutrition **50**(11): 772-774.

Ginger (***Zingiber officinale*** Roscoe) has been claimed to exert an anti-thrombotic effect in humans as ginger extracts inhibit cyclo-oxygenase activity of platelets in vitro. Effects of ginger consumption on ex vivo platelet function, however, are contradictory. Authors therefore investigated whether daily consumption of raw or cooked ginger decreases platelet cyclo-oxygenase activity all assessed by ex vivo maximally stimulated platelet thromboxane B2 production. Design: Authors carried out a randomized placebo-controlled cross-over study of 3 x 2 weeks. Subjects: Eighteen healthy volunteers aged 22 ± 3 y (mean ± s.d.) participated in the study; there were no dropouts. Interventions: Subjects consumed 15 g of raw ginger root, 40 g of cooked stem ginger, or placebo daily for two weeks. Authors took fasted venous blood samples and measured thromboxane B2 production in maximally stimulated platelet-rich plasma at days 12 and 14 of each treatment period. Results: Mean decrease in thromboxane production relative to placebo was 1 ± 9% for ginger root, and -1 ± 8% for stem ginger, with no effect of treatment order (P = 0.984). Study did not confirm the putative anti-thrombotic activity of ginger in humans.

107. Jayashankar, S., G. J. Panagoda, E. A. Amaratunga, K. Perera and P. S. Rajapakse (2011). "**A randomised double-blind placebo-controlled study on the effects of a herbal toothpaste on gingival bleeding, oral hygiene and microbial variables.**" The Ceylon medical journal **56**(1): 5-9.

Different systems of traditional medicine of the Indian subcontinent, have used *Acacia chundra* Willd, *Adhatoda vasica* Nees., *Mimusops elengi* L., ***Piper nigrum*** L., *Pongamia pinnata* L. Pirerre, *Quercus infectoria* Olivier., *Syzygium aromaticum* L., ***Terminalia chebula*** Retz., ***Zingiber officinale*** Roscoe., individually or in combinations, to cure oral diseases. To investigate the oral hygiene and gingival health benefits of toothpaste formulated with a mixture of the above herbs (15% w/w). Sixty participants (test n = 30, control n = 30, mean age 23.6 +/- 2.25 vs 23.9 +/- 3.2 years) who fulfilled the selection criteria and had similar plaque (1.734 +/- 0.29 vs 1.771 +/- 0.33) and percentage of sites with gingival bleeding (19.6 +/- 7 vs 20.7 +/- 8) were studied in a double blind randomised clinical trial. Brushing instructions to all and a scaling for those with calculus were provided two weeks before baseline examination. One ml of resting saliva was collected to ascertain anaerobic (SAnB) and aerobic (SAB) bacterial counts, plaque index (PI), percentage sites with bleeding on probing (BOP) and pocket depth (PD) (at 6 sites/tooth) were recorded at baseline, followed by home use of the allocated toothpaste (test or placebo) twice a day for 12 weeks. Measurements were repeated at 4, 8, and 12 weeks. PI, BOP and SAnB decreased significantly in the test group at 4, 8, and 12 weeks compared to baseline measurements (Wilcoxon-Signed Rank Test, $p < 0.01$). There was no statistically significant improvement in PI, BOP, and SAnB in the placebo group. The study indicates the beneficial effects of this herbal toothpaste (Sudantha)

on oral hygiene and gingival health variables when compared with the placebo. Further clinical trials using patients with gingivitis are necessary to confirm the therapeutic benefits of this herbal toothpaste.

108. Jeeth, A., D. D. Aloknatha, S. V.S and Shreevathsa (2014). "**Utility of bheshaja sevana kala–Open end comparative randomized clinical trial.**" Journal of Ayurveda and Holistic Medicine (JAHM) **2**(7): 4-7.

Bheshaja sevana kala is the principle of time of administration of the medicine. Drug exhibits different actions when administered in different bheshaja sevana kala (time of administration of medicine). Actual aim of bheshaja sevana kala is to provide the fulfillment towards desired action of drug administration in patient in order to pacify the disease. Considering these factors the present study was intended to evaluate the efficacy of bheshaja sevana kala in the disease prameha (diabetes mellitus). Guduchi (***Tinospora cordifolia***) is said to mitigate all types of prameha (diabetes mellitus). According to Sushrutasamhitha, the disease pramehais vyana and apanavata (types of vata- a bodily humour) involved disease. The cardinal symptoms of prameha simulate with the symptoms of diabetes mellitus. Hence the disease diabetes mellitus type II was selected to assess the role of pragbhaktha (before food), pratahaadhobhakta (morning after food) bheshaja sevana kala which are the time of administration of medicine for vyana and panavata involvement respectively. A randomized clinical study was outlined with a pre, mid and post test assessment of 30 patients satisfying the inclusion criteria who were randomly selected. In the present study 15 patients were asked to consume 4gm of guduchichurna (powder of *Tinospora cordifolia*) in pragbhakta (before food) and pratahadhobhaktakala (morning after food) with lukewarm water and another 15 patients were asked to take 4gm of guduchi churna three times a day after food with lukewarm water for the duration of 30 days. After intervention, results were analyzed statistically using descriptive statistics, chi square test, paired samples't' test, repeated measure ANOVA, using SPSS for windows software. Fairly good results were observed in all the parameters of the study. There was no much difference in the result between the groups with regards to subjective parameters i.e. prabhootamootrata (polyurea), pipasa (polydypsia), kshuda (polyphagia), swedapravrutti (excessive sweating), karapadadaha (burning sensation in palms and soles), supti (numbness) and klama (fatigue). With regards to FBS and PPBS patients of group A showed better result than group B, but it was statistically insignificant (P value > 0.05) between the groups. In case of avilamootrata (urine turbidity), also group A showed better result than group B and the result was statistically significant (P value 0.002). Conclusion is that Guduchi churna (powder of *Tinospora cordifolia*) administered during appropriate time showed statistically significant result in subsiding the cardinal symptomof pramehai.e. avilamootrata (urine turbidity).

109. Jin, C. Q., Y. X. Jia, H. X. Dong, J. W. Zhou, G. F. Sun, Y. Y. Zhang, Q. Zhao and B. Y. Zheng (2013). "**Stir-fried white pepper can treat diarrhea in infants and children efficiently: A randomized controlled trial.**" American Journal of Chinese Medicine **41**(4): 765-772.

Authors evaluated the efficacy and safety of stir-fried white pepper (***Piper nigrum***) in the treatment of infant and children diarrhea. This was a randomized trial conducted in the pediatric emergency department of the hospital affiliated to Jining Medical

College. One hundred seventy four patients were selected from outpatients from 2011 to 2012. Participants were randomly assigned to treatment with stir-fried white pepper (n = 88) or montmorillonite powder (n = 86). The proportions of chronic diarrhea patients (n = 52) showing success of treatment were similar for both groups. There were great differences between the two groups in acute diarrhea (n = 62) and persistent diarrhea (n = 60), and the cure rate of stir-fried white pepper was higher than montmorillonite powder in both groups. The prescription of stir-fried white pepper significantly decreased the frequency of diarrhea in infants and children under 2.5 years with diarrhea compared to treatment with montmorillonite powder, especially for the patients with acute diarrhea or persistent diarrhea.

110. Kalikar, M., V. Thawani, U. Varadpande, S. Sontakke, R. Singh and R. Khiyani (2008). "**Immunomodulatory effect of *Tinospora cordifolia* extract in human immuno-deficiency virus positive patients.**" Indian Journal of Pharmacology **40**(3): 107-110.

To assess the safety and efficacy of TCE in human immuno-deficiency virus positive patients. Efficacy of ***Tinospora cordifolia*** extract (TCE) in HIV positive patients was assessed in randomized double blind placebo controlled trial. 68 HIV positive participants were randomly assigned to two groups to receive either TCE or placebo for six months. After clinical examination TLC, DLC, ESR, platelet count, hemoglobin and CD4 count were done. The hematological investigations were repeated at bimonthly intervals and CD4 count was repeated at the end of the study. Patients were clinically reviewed at monthly intervals for compliance, refill and ADR monitoring. The drugs were decoded at the end of the trial. TCE treatment caused significant reduction in eosinophil count and hemoglobin percentage. 60% patients receiving TCE and 20% on placebo reported decrease in the incidence of various symptoms associated with disease. Some of the common complaints reported by patients on TCE were anorexia, nausea, vomiting and weakness. *Tinospora cordifolia* extract, a plant derived immunostimulant, significantly affected the symptoms of HIV. This was validated by clinical evaluation. However not all of the objective parameters studied by us, back this up. *Tinospora cordifolia* could be used as an adjunct to HIV/AIDS management.

111. Kalra, V., H. Zamir, R. Pandey and K. S. Kulkarni (2002). "**A randomized double blind placebo-controlled drug trial with Mentat in children with attention deficit hyperactivity disorder.**" Neurosciences Today **6**(4): 223-227.

A randomized double blind placebo-controlled trial was conducted to evaluate the efficacy of Mentat, an herbal formulation, in school going children with Attention Deficit Hyperactivity Disorder (ADHD). A total of 195 children were screened, out of which 60 satisfied the DSM-IV criteria for ADHD. Among those enrolled in the study, 30 received Mentat and 30 received placebo. An assessment of academic functioning along with psychological tests was done before and after the treatment. Malin's Intelligence Scale for Indian Children (MISIC), Conner's 10 point rating scale, Kaufman Assessment Battery for Children (KABC) and brain SPECT (Simple Photon Emission Computed Tomography) scans and subtests were assessed. Six children were dropped from the study, as they were lost to follow-up and another 4 children showed variable results. Thus, statistical analysis was carried out in only 50 children. The Conner's test and Gestalt closure subtest of KABC showed a statistically

significant improvement in the Mentat group as compared to the placebo group. Pre- and post-SPECT scan observations showed improvement in three children in the Mentat group as compared to one child in the placebo group. For all other tests, no significant difference was found between the Mentat and placebo groups. Composition of each Mentat tablet (Botanical names): Extracts: *Bacopa monnieri* (136 mg), *Centella asiatica* (70 mg), ***Withania somnifera*** (52 mg), *Evovulus alsinodes* (52 mg), *Nardostachys jatamansi* (52 mg), *Valeriana wallichii* (50 mg), *Embelia ribes* (50mg), *Prunus amygdalus* (50 mg), ***Tinospora cordifolia*** (36 mg), ***Terminalia chebula*** (36 mg), ***Emblica officinalis*** (36 mg), *Oroxylum indicum* (32 mg) and *Celastrus paniculatus* (32 mg). Powders: *Bacopa monnieri* (80mg), *Orchis mascula* (18mg), *Mucuna pruriens* (18 mg), *Elettaria cardamomum* (18 mg), *Terminalia arjuna* (18 mg), *Foeniculum vulgare* (18mg), *Ipomoea digitata* (18 mg), ***Zingiber officinale*** (14 mg), ***Terminalia bellirica*** (14 mg), *Myristica fragrans* (14 mg), *Syzygium aromaticum* (10 mg) and Mukta pishti (3 mg).

112. Kamal, R. and S. Aleem (2009). "**Clinical evaluation of the efficacy of a combination of zanjabeel (*Zingiber officinale*) and amla (*Emblica officinalis*) in hyperlipidaemia.**" Indian Journal of Traditional Knowledge **8**(3): 413-416.

In Unani System of Medicine, many drugs (single drugs as well compound formulations) are used for the purpose of reducing body weight and treating the obesity (Muhazzil). Indian gooseberry (amla ***Emblica officinalis***) & ginger (Zanjabeel ***Zingiber officinale***) are among these medicines. Since these drugs are useful in obesity, these can also be proved beneficial in lowering increased concentration of plasma lipids or treating hyperlipidaemia. Their efficacy has also been proved pharmacologically and these are documented as good hypolipidaemic as well as antioxidant natural agents. The combination of drugs was found to be significant in lowering the level of serum total cholesterol, serum tryglycerides, serum LDL-cholesterol, serum VLDL-cholesterol and in increasing the level of serum HDL-cholesterol in patients of primary hyperlipidaemia.

113. Kamali, S. H., A. R. Khalaj, S. Hasani-Ranjbar, M. M. Esfehani, M. Kamalinejad, O. Soheil and S. A. Kamali (2012). "**Efficacy of 'Itrifal Saghir', a combination of three medicinal plants in the treatment of obesity; A randomized controlled trial.**" DARU, Journal of Pharmaceutical Sciences **20**(1).

Herbal combination of Itrifal Saghir or ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***) has been widely used in traditional medicine. And brings health benefits such as antioxidant effect and scavenger of hydroxyl radicals and nitric oxide radicals activity and substantiated in traditional medicine a anti-obesity. In this study authors aimed to assess the efficacy of this herbal medicinal on reduction of weight and body mass index (BMI) of simple obese subjects in comparison with placebo. Obese subjects aged between 16 and 60 years were selected for 12-week, double-blind, randomized, placebo-controlled trial using a parallel design. Subjects were randomly assigned to take 5 grams of either the Itrifal Saghir (n = 31) or placebo (n = 31), 2 times daily for 12 weeks. Measures of body weight, BMI, waist circumference (WC), hip circumference (HC), were assessed at baseline and once every four weeks during the 12 week treatment period. The safety was evaluated by means of measuring the liver and kidney function. Homeostasis

model of insulin resistance (HOMA-IR) was calculated as [fasting insulin (µU/mL) × fasting glucose (mmol/L)/22.5]. Compared to placebo group, in treatment group the mean difference of effective weight loss was 4.82Kg (CI95% 3.52 - 6.11, ρ < 0.001), the mean of decrease in waist circumference was 4.01 cm (CI 95% 2.13 - 5.90, ρ < 0.001), and the mean decrease in hip circumference was 3. 21 cm (CI 95% 1.96 - 4.45, ρ < 0.001) in treated subjects. No adverse effects or significant changes in liver and kidney function tests were observed in both placebo and treated groups. Itrifal Saghir appears to produce a positive effect on weight loss in obese subjects.

114. Karkal, Y. R. and L. K. Bairy (2007). "**Safety of aqueous extract of *Tinospora cordifolia* (Tc) in healthy volunteers: A double blind randomised placebo controlled study.**" Iranian Journal of Pharmacology and Therapeutics **6**(1): 59-61.

It is a common misconception that ayurvedic medicines (traditional Indian system of medicine) are always safe. In fact, they also pose serious health risks either in the form of adverse reactions or in the form of drug interactions. Over 80% of our population takes ayurvedic medicines. The study was aimed to evaluate the safety profile of ***Tinospora cordifolia*** in healthy volunteers using a battery of haematological, and biochemical tests and open questionnaire method. Thirty healthy volunteers (males - 22 and females - 8) aged 18 - 30 years (mean 22.5 ± 0.28) who volunteered to participate were studied in a randomized, double - blind, placebo controlled design. The volunteers were provided with 21 days of medication (coded box) containing *Tinospora cordifolia* 500 mg or matching placebo. One tablet of *Tinospora cordifolia* of 500 mg strength or placebo was taken once daily orally in the morning along with breakfast for 21 days. The safety assessment was done with the help of haematological and biochemical investigations which were assessed before and after the medication by unpaired t test. 'Unpaired t test' using SPSS computer software package. Analysis of the various lab values between the control and the test group before and after taking the drug/placebo by unpaired 't' test shows no significant difference between the groups (p = > 0.05). Hence it can be concluded that *Tinospora cordifolia* is safe at a dose of 500 mg per day for a period 21 days in healthy volunteers for the parameters studied.

115. Kashefi, F., M. Khajehei, M. Alavinia, E. Golmakani and J. Asili (2014). "**Effect of ginger (*Zingiber officinale*) on heavy menstrual bleeding: A placebo-controlled, randomized clinical trial.**" Phytotherapy Research **29**(1): 114-119.

A wide range of herbal plants have been reported to treat various gynecological problems of women. This study was set out to investigate the effect of ginger (***Zingiber officinale***) on heavy menstrual bleeding (HMB) in high school girls. Ninety-two young women who experienced HMB and met the inclusion criteria were recruited in this study. Participants were evaluated for six consecutive menstrual cycles. During 3 assessment cycles, their HMB was confirmed by Pictorial Blood Assessment Chart. They were then randomly allocated to two study groups to receive either ginger or placebo capsules. The participants filled in the same chart during three intervention cycles. Results: The level of menstrual blood loss dramatically declined during the three intervention cycles in ginger-receiving group. The decrease of blood loss in ginger-receiving group was significantly more remarkable than that of participants receiving placebo (p < 0.001). Minimum number of participants

reported adverse effects. HMB is highly prevalent among young women. Considering the significance of appropriate and timely treatment and also the importance of prevention of unwanted consequences, ginger may be considered as an effective therapeutic option for HMB.

116. Katakdound, S. D. (2015). "**A randomised controlled clinical trial to evaluate effect of Ayurvedic formulation in postnatal care.**" Journal of Ayurveda and Holistic Medicine (JAHM) **3**(1).

Aim was to evaluate postnatal care with Ayurvedic medicine as the basic concept behind this clinical trial. In the present study 20 uncomplicated vaginally delivered patients with episiotomy were taken from the study centre and divided into two groups. In Group A (n=10) patients were treated with Gandhak Rasayanavati, Sookshma ***Triphalavati*** & ***Triphala*** **Kwath** containing ***Emblica officinalis*****,** ***Terminalia chebula*****,** ***Terminalia bellirica*** & in Group B (n=10) Tab. Ciprofloxacin + Tinidazole (500+200) mg, Tab Serratiopeptidase 10mg, Betadine ointment & liquid Dettol for 7 days and results were observed. In observation clinical findings were noted on 0th,3rd, 6th & 9th day. Statistical analysis used: The improvement in the cardinal symptoms were compared and analyzed statistically between the end of the treatment and baseline by using student's paired 't' test. The investigations also analyzed using student's unpaired 't' test. Results: In the GroupA no generalized or localized sepsis observed in any patient. Quality of wound healing, involution of uterus, nature of lochia and local tenderness shows statistically equal 't' value i.e. 0, 0.710, 0.534 and 0.599 respectively when compared with GroupB. It can be concluded that the Ayurvedic drugs are significantly effective in postnatal care when compared with modern drugs to combat infections. Hence Gandhak Rasayanavati, Sookshma *Triphala*vati & *Triphala* Kwath is reliable to use in postnatal care.

117. Keating, A. and R. A. Chez (2002). "**Ginger syrup as an antiemetic in early pregnancy.**" Alternative Therapies in Health and Medicine **8**(5): 89-91.

Ginger (***Zingiber officinale***) has been used to ameliorate symptoms of nausea. A beverage containing ginger in a syrup may be easier to consume than a capsule or solid food. Objective was to determine if ginger syrup mixed in water is an effective remedy for the relief of nausea and vomiting in the first trimester of pregnancy. Design was double-blind, placebo-controlled, randomized clinical trial. Subjects were enrolled from the University of South Florida department of obstetrics and gynecology private practice office. Patients were 26 subjects in the first trimester of pregnancy. Intervention: Subjects ingested 1 tablespoon of commercially prepared study syrup (or placebo) in 4 to 8 ounces of hot or cold water 4 times daily. Main Outcome Measures were taken as duration and severity of nausea and vomiting over a 2-week period measured on a 10-point scale. Results suggest that after 9 days, 10 of the 13 (77%) subjects receiving ginger had at least a 4-point improvement on the nausea scale. Only 2 of the 10 (20%) remaining subjects in the placebo group had the same improvement. Conversely, no woman in the ginger group, but 7 (70%) of the women in the placebo group, had a 2-point or less improvement on the nausea scale. Eight of the 12 (67%) women in the ginger group who were vomiting daily at the beginning of the treatment stopped vomiting by day 6. Only 2 of the 10 (20%) women in the placebo group who were vomiting stopped by day 6. Thus, the

ingestion of 1 g of ginger in syrup in a divided dose daily may be useful in some patients experiencing nausea and vomiting in the first trimester of pregnancy.

118. Keche, Y., V. Badar and M. Hardas (2010). "**Efficacy and safety of Livwin (polyherbal formulation) in patients with acute viral hepatitis: A randomized double-blind placebo-controlled clinical trial.**" International Journal of Ayurveda Research **1**(4): 216.

The study was planned to evaluate the efficacy and safety of Livwin (polyherbal formulation) in acute viral hepatitis. In this study, there were 29 patients in each group, receiving either Livwin or placebo capsules containing lactose powder (500 mg). Livwin is polyherbal formulation that contains extracts of seven medicinal plants as follows: Arjuna (*Terminalia arjuna* W and A) - 100 mg, Ashwagandha (***Withania somnifera*** Dunal) - 100 mg, Bhumyamalaki (*Phyllanthus niruri* Linn) - 100 mg, Daruharidra (*Berberis aristata* DC) - 50 mg, Guduchi (***Tinospora cordifolia*** (Willd.) Miers) - 75 mg, Kutki (*Picrorhiza kurroa* Royle ex Benn.) - 50 mg, Punarnava (*Boerhaavia diffusa* Linn) - 50 mg. Placebo capsule was containing lactose powder 500 mg. Both drugs were given orally two capsules two times a day for eight weeks followed by treatment free period of four weeks. Recovery of patients was assessed by noting symptomatic recovery and by measuring levels of serum bilirubin, serum aspartate aminotransferase (AST), serum alanine aminotransferase (ALT), alkaline phosphatase at baseline, 2, 4, 8 and 12 weeks. Significant earlier recovery of weakness was observed with Livwin as compared to placebo at 2, 4 and 8 weeks. Serum bilirubin and ALT was observed in normal range in significantly more number of patients with Livwin treatment as compared to placebo at 2, 4 and 8 weeks. AST was observed in normal range in significantly more number of patients with Livwin treatment as compared to placebo at 2 and 4 weeks. Livwin is found effective in uncomplicated patients of acute viral hepatitis. Epigastric pain and diarrhea were reported with Livwin treatment.

119. Kessler, C., L. Pinders, A. Michalsen and H. Cramer (2015). "**Ayurvedic interventions for osteoarthritis: a systematic review and meta-analysis.**" Rheumatology International **35**(2): 211-232.

Ayurveda is one of the fastest growing systems within complementary and alternative medicine. However, the evidence for its effectiveness is unsatisfactory. The aim of this work was to review and meta-analyze the effectiveness and safety of different Ayurvedic interventions in patients with osteoarthritis (OA). 138 electronic databases were searched through August 2013. Randomized controlled trials, randomized crossover studies, cluster-randomized trials, and non-randomized controlled clinical trials were eligible. Adults with pre-diagnosed OA were included as participants. Interventions were included as Ayurvedic if they were explicitly labeled as such. Main outcome measures were pain, physical function, and global improvement. Risk of bias was assessed using the Cochrane risk of bias tool. 19 randomized and 14 non-randomized controlled trials on 12 different drugs and 3 non-pharmaceutical interventions with a total of 2,952 patients were included. For the compound preparation, Rumalaya, large and apparently unbiased effects beyond placebo were found for pain (standardized mean difference [SMD] −3.73; 95 % confidence interval [CI] −4.97, −2.50; $P < 0.01$) and global improvement (risk ratio 12.20; 95 % CI 5.83, 25.54; $P < 0.01$). There is also some evidence that effects of the herbal compound

preparation Shunti-Guduchi are comparable to those of glucosamine for pain (SMD 0.08; 95 % CI −0.20, 0.36; P = 0.56) and function (SMD 0.15; 95 % CI −0.12, 0.36; P = 0.41). Based on single trials, positive effects were found for the compound preparations RA-11, Reosto, and Siriraj Wattana. For *Boswellia serrata*, *Lepidium sativum*, a *Boswellia serrata* containing multicomponent formulation and the compounds Nirgundi Taila, Panchatikta Ghrita Guggulu, and Rhumayog, and for non-pharmacological interventions like Ayurvedic massage, steam therapy, and enema, no evidence for significant effects against potential methodological bias was found. No severe adverse events were observed in all trials. The drugs Rumalaya and Shunti-Guduchi (***Zingiber officinale*** & ***Tinospora cordifolia***) seem to be safe and effective drugs for treatment of OA-patients, based on these data. However, several limitations relate to clinical research on Ayurveda. Well-planned, well-conducted and well-published trials are warranted to improve the evidence for Ayurvedic interventions.

120. Khan, M. S. and A. N. Ansari (2015). "**Effect of leech therapy (Irsal-e Alaq) and Unani formulation (Itrifal Sagheer with Zanjabeel) in the management of varicose veins (Dawali): An open, randomized, standard controlled, three groups clinical trial.**" Spatula DD-Peer Reviewed Journal on Complementary Medicine and Drug Discovery **5**(1): 41-50.

Varicose veins affect up to 5% or more of the adult population of western countries and 15 to 20% of general population. The inability to perform heavy and prolonged standing works affects the quality of life, and earning capacity of patients as well. Unani physicians have described this disease as Dawali and have been treating the disease since ancient times effectively on the principle of evacuation (Tanqiya), restoration (Ta'deel) and potentiation (Taqwiyat). The limitation of conventional treatment in the management of varicose veins paved the way to evaluate the efficacy and safety of leech therapy and a pharmacopoeial Unani poly herbal formulation in the management of varicose veins on scientific parameters. The study was conducted as open, randomized, standard controlled, three groups clinical trial on 30 eligible patients. Leech therapy was selected as a treatment procedure in the test group 'A'. The combination of Unani formulation Itrifal Sagheer with Zanjabeel and leech therapy was selected as a treatment strategy in the test group 'B'. Compression stocking was selected as a standard treatment procedure in the control group 'C'. Significant statistical difference was observed in subjective and objective parameters. Almost all patients reported improvement in pain and heaviness. The more promising result was observed in group 'A' in pain (82%), where group 'B' showed more marked response (64%) in heaviness among all the groups. In intra group comparisons, statistically highly significant difference was observed from baseline to 14th day to 28th day (P<0.001) on Revised VCSS in both groups 'A' and 'B', But the mean difference was more in group 'B' (5.36) than in 'A' (4.53). In group 'C', the mean difference was (-1.60). Highly significant change was also observed in vein diameter below knee and above ankle in group 'A' and group 'B', while no significant change was demonstrable in group 'C'. No significant change was found in safety parameter. The trial regimen of leech therapy and Unani formulation Itrifal Sagheer (including ***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) with Zanjabeel (***Zingiber officinalis***) was found safe and effective in the treatment of varicose veins, predominantly in pain, heaviness, swelling, skin changes and vein diameter.

121. Khan, S. and M. J. Balick (2001). "**Therapeutic plants of Ayurveda: A review of selected clinical and other studies for 166 species.**" Journal of Alternative and Complementary Medicine **7**(5): 405-515.

This paper reports on the results of a literature survey involving 166 different species of plants used in the Ayurvedic pharmacopoeia, based on a sampling of the literature available to us. Auyjors found a wide range of clinical and other in vivo studies for many of the plant-based therapies utilized in the Ayurvedic system. Of the 166 plants investigated, 72 (43%) had at least one or more human studies and 103 (62%) had one or more animal studies. These results appear to contradict the generally held notion that herbal remedies used in non-Western systems of botanical medicine have not been evaluated in human or in vivo trials. Some of these studies are not always as large or methodologically rigorous as clinical studies reported in major medical journals. Indeed, a critical assessment of the research according to the standards of evidence-based medicine would eliminate many of these studies for lack of rigor according to criteria of randomization, sample size, adequacy of controls, etc. However, the studies do suggest which species might be appropriate for larger and better-controlled trials in the future. Accordingly, a synopsis of the plants, their therapeutic applications, and their clinical or experimental evaluations is presented. [**Note by the editors**: In this 15 years old study, from the relevance of JVN-8, the species investigated are ***Emblica officinalis*** (Gastrointestinal disease, Serum cholesterol levels, Viral hepatitis), ***Piper longum*** (increase in the bioavailability of drugs, disappearance of Giardia lamblia), ***Piper nigrum*** (no damage to human gastric mucosa), ***Terminalia bellirica*** and ***Terminalia chebula*** (achne vulgaris, congestive cardiac failure), ***Tinospora cordifolia*** (calculi on kidney or urinary bladder, management of obstructive jaundice), ***Withania somnifera*** (Calculi on kidney and urinary bladder, osteoarthritis, psychomotor performance, rheumatoid arthritis), ***Zingiber officinale*** (many studies)].

122. Khandouzi, N., F. Shidfar, A. Rajab, T. Rahideh, P. Hosseini and M. M. Taheri (2015). "**The effects of ginger on fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein A-I and malondialdehyde in type 2 diabetic patients.**" Iranian Journal of Pharmaceutical Research **14**(1): 131-140.

Diabetes mellitus is the most common endocrine disorder, causes many complications such as micro- and macro-vascular diseases. Anti-diabetic, hypolipidemic and anti-oxidative properties of *ginger* (***Zingiber officinale***) have been noticed in several researches. The present study was conducted to investigate the effects of ginger on fasting blood sugar, Hemoglobin A1c, apolipoprotein B, apolipoprotein A-I, and malondialdehyde in type 2 diabetic patients. In a randomized, double-blind, placebo-controlled, clinical trial, a total of 41 type 2 diabetic patients randomly were assigned to ginger or placebo groups (22 in ginger group and 19 in control group), received 2 g/day of ginger powder supplement or lactose as placebo for 12 weeks. The serum concentrations of fasting blood sugar, Hemoglobin A1c, apolipoprotein B, apolipoprotein A-I and malondialdehyde were analyzed before and after the intervention. Ginger supplementation significantly reduced the levels of fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein B/apolipoprotein A-I and malondialdehyde in ginger group in comparison to

baseline, as well as control group, while it increased the level of apolipoprotein A-I ($p<0.05$). It seems that oral administration of ginger powder supplement can improves fasting blood sugar, hemoglobin A1c, apolipoprotein B, apolipoprotein A-I, apolipoprotein B/apolipoprotein A-I and malondialdehyde in type 2 diabetic patients. So it may have a role in alleviating the risk of some chronic complications of diabetes.

123. Khanna, S., A. Das, J. Spieldenner, C. Rink and S. Roy (2015). "**Supplementation of a standardized extract from *Phyllanthus emblica* improves cardiovascular risk factors and platelet aggregation in overweight/class-1 obese adults.**" Journal of Medicinal Food **18**(4): 415-420.

The objective of this study (clinicaltrials.gov NCT01858376) was to determine the effect of oral supplementation of a standardized extract of ***Phyllanthus emblica*** (CAPROS®) on cardiovascular disease (CVD) risk factors in overweight adult human subjects from the US population. Overweight/Class-1 obese (body-mass index: 25-35) adult subjects received 500 mg of CAPROS supplement b.i.d for 12 weeks. The study design included two baseline visits followed by 12 weeks of supplementation and then 2 weeks of washout. At all visits, peripheral venous blood was collected in sodium citrate tubes. Lipid profile measurements demonstrated a significant decrease in calculated low-density lipoprotein cholesterol and total cholesterol/high-density lipoprotein following 12 weeks of CAPROS supplementation when compared to averaged baseline visits. Circulatory high-sensitivity C reactive protein (hs-CRP) levels were significantly decreased after 12 weeks of supplementation. In addition, both ADP-and collagen-induced platelet aggregation was significantly downregulated following 12 weeks of supplementation. Overall, the study suggests that oral CAPROS supplementation may provide beneficial effects in overweight/Class-1 obese adults by lowering multiple global CVD risk factors.

124. Kishore, R. K., H. A. Abhishekh, K. Udupa, J. Thirthalli, G. S. Lavekar, B. N. Gangadhar, T. R. Raju and T. N. Sathyaprabha (2014). "**Evaluation of the influence of ayurvedic formulation (Ayushman-15) on psychopathology, heart rate variability and stress hormonal level in major depression (Vishada).**" Asian Journal of Psychiatry **12**(1): 100-107.

Ayurveda (Indian-complimentary and alternative medicine) is still most sought after in India and has promising potential in management of Vishada [major depressive disorder (MDD)]. But, systematic research is lacking. In this study authors evaluated of influence of ayurvedic treatment (Panchakarma and Ayushman-15) on psychopathology, heart rate variability (HRV) and endocrinal parameters in patients with major depression. Method: 81 drug naive patients diagnosed as Vishada by ayurvedic physician and MDD according to DSM IV-TR were given ayurvedic Virechana module (therapeutic purgation) and were randomized into two groups. Patients in group A (n= 41) received Ayushman-15A while group B (n= 40) received Ayushman-15B for two months and Shirodhara (forehead-oil pouring therapy). Patients were assessed with Hamilton Depression Rating Scale (HDRS), Montgomery Asberg Depression Rating Scale (MADRS), Heart Rate Variability (HRV). Cortisol and adrenocorticotropic hormone (ACTH) were estimated at baseline and after ayurvedic therapy. HRV and endocrinal parameters were compared with age and gender matched healthy volunteers. Results: HRV parameters showed significant sympathetic dominance in patients compared to healthy volunteers. Two months of ayurvedic

treatment significantly decreased psychopathology, showed increase in vagal tone, decrease in sympathetic tone and reduced cortisol levels. However, there was no significant difference between groups receiving Ayushman A and B. Conclusion is that there is evidence for antidepressant, cardiac (HRV) and beneficial neuroendocrine modulatory influence of Ayurveda therapy in patients of Vishada (MDD). Further studies are needed to confirm these findings. Greater insight into the neurobiology behind this therapy might provide valuable information about newer drug target.

125. Kizhakkeveettil, A., P. S. Jayagopal and K. Rose (2011). "**Hypercholesterolemia and Ayurvedic Medicine: A Case Report.**" Topics in Integrative Health Care **2**(2): ID: 2.2006.

Over the last two decades there has been an increasing emphasis placed on screening for high cholesterol and adopting interventions to reduce cholesterol levels in order to reduce the risk of heart disease. The high costs and side effects of hypercholesterolemia medications have led many people to search for alternate treatments. Only a few studies have been conducted to evaluate the effect of Ayurvedic herbal medicine formulae on hypercholesterolemia. The objective of this article is to describe a case where Ayurvedic herbs appeared to have been helpful in the management of hypercholesterolemia. Clinical Features: This patient was a 46-year-old woman who had been diagnosed with hypercholesterolemia two years prior to presentation. She had not responded to conventional treatment. She was treated for eight months with the Ayurvedic formulae Kaishora Guggulu, ***Triphala*** and a custom made herbal tea mix. Ayurvedic treatment for this patient consisted solely of the use of herbal formulae over an eight-month period. Three preparations were prescribed for the first 4 months. 1.Kaishora Guggulu: This formula consists of the following ingredients: Haritaki Fruit (***Terminalia chebula***), Vibhitaki Fruit (***Terminalia bellirica***), Amalaki Fruit (***Emblica officinalis***), Guduchi Stem (***Tinospora cordifolia***), Ginger Root (***Zingiber officinale***), Pippali Fruit (***Piper longum***), Black Pepper Fruit (***Piper nigrum***), Vidanga (*Embelia ribes*), Danti Root (*Baliospermum montanum*), Trivruth Root (*Operculina turpethum*), Guggulu Resin (*Commiphora mukul*), The patient was prescribed four 300 mg tablets per day. Two tablets were taken after breakfast and two tablets after dinner. 2. *Triphala* : This formula consists of the following ingredients: Haritaki Fruit (*Terminalia chebula*), Vibhitaki Fruit (*Terminalia bellirica*), Amalaki Fruit (*Emblica officinalis).* The patient was prescribed three 300 mg tablets per day to be taken after dinner. 3. Custom prepared Herbal Tea blend: This formula consists of the following ingredients: *Coriandrum sativuam* -1TBS, *Cuminum cyminum* -1TBS, *Foeniculum vulgare*- 1 TBS, *Curcuma longa* -1/2 TBS, *Elettaria cardamomum* -1/2TBS. Her total cholesterol dropped from 270 to 208 mg/dl, her LDL dropped from 191 to 146 mg/dl, and her HDL rose from 57 to 63 mg/dl. There were no side effects reported. This case demonstrates the use of Ayurvedic herbs in the management of hypercholesterolemia. Further high quality studies with randomized clinical trials should be conducted to better understand the effectiveness of Ayurvedic treatment for hypercholesterolemia.

126. Klassen, T. P., B. Pham, M. L. Lawson and D. Moher (2005). "**For randomized controlled trials, the quality of reports of complementary and alternative medicine was as good as reports of conventional medicine.**" Journal of Clinical Epidemiology **58**(8): 763-768.

Objective was to compare the quality of reporting of reports randomized controlled trials (RCTs) published in English and in languages other than English (LOE), and to determine whether there were differences between conventional medicine (CM) and complementary and alternative medicine (CAM) reports. Study Design and Setting: Authors examined more than 600 RCTs associated with 125 systematic reviews. They extracted characteristics of each RCT using a standardized data collection form. Quality was assessed using the Jadad scale and the adequacy of allocation concealment. Results: There were only minor differences in the quality of reports of RCTs published in English compared with other languages (median quality score of 3 vs. 2, P = .10), and the quality of reports of CAM RCTs was similar to the CM reports (median score of 3 vs. 2, P = .14). There was no effect of language of publication on quality of reporting for CM trials (median score of 2 vs. 2, P = .12). Among CAM trials, however, overall quality scores were higher for reports in English than for reports in other languages (median score of 3 vs. 2, P = .04). The overall quality of reports published in languages other than English is similar to that of English-language reports. Moreover, the overall quality of reporting of RCTs of CAM interventions is as good as that for CM interventions.

127. Krishnamurthy, M. N. and S. Telles (2007). "**Assessing depression following two ancient Indian interventions: Effects of Yoga and Ayurveda on older adults in a residential home.**" Journal of Gerontological Nursing **33**(2): 17-23.

The effects of yoga and ayurveda on geriatric depression were evaluated in 69 persons older than 60 who were living in a residential home. Participants were stratified by age and gender and randomly allocated to three groups: Yoga, Ayurveda, or Wait-list Control. The 15-item Geriatric Depression Scale was used to assess depressive symptoms prior to the intervention, and after 3 months and 6 months post-intervention. Participation in one of the three groups lasted 24 weeks. The yoga program (7 hours 30 minutes per week) included physical postures, relaxation techniques, regulated breathing, devotional songs, and lectures. The Ayurveda Group received an herbal preparation with ***Emblica officinalis***, ***Withania somnifera*** and ***Piper*** etc. twice daily for the whole period. The depression symptom scores of the Yoga Group at both 3 and 6 months decreased significantly, from a group average baseline of 10.6 to 8.1 and 6.7, respectively ($p < .001$, paired t-test). The other groups showed no change. Hence, an integrated approach of yoga including the mental and philosophical aspects in addition to the physical practices was useful for institutionalized older persons.

128. Kuchewar, V. V., M. A. Borkar and M. A. Nisargandha (2014). "**Evaluation of antioxidant potential of Rasayana drugs in healthy human volunteers.**" AYU **35**(1): 46–49.

It is increasingly being realized that many of today's diseases are due to "oxidative stress" that results from an imbalance between formation and neutralization of free radicals. Rasayana Chikitsa is a unique branch of Ayurveda. The word Rasayana means the way for attaining excellent Rasadi Dhatus. Several medicinal plants have been described as Rasayanas in Ayurveda. Ashwagandha and Guduchi are the best among the Rasayanas described by Charaka. Ashwagandha (***Withania somnifera*** (L.) Dunal.), is also known as Indian ginseng, or winter cherry. It has been an important herb in the Ayurvedic and indigenous medical systems for over 3000 years. Guduchi

(***Tinospora cordifolia*** (Thunb.) Miers.) has been used in Ayurvedic preparations for the treatment of various ailments throughout the centuries.The aim was to study the efficacy of Ashwagandha and Guduchi in oxidative stress in healthy volunteers. The study was carried out on 30 healthy volunteers after obtaining written informed consent. They were randomly distributed in three groups. Each group was treated with three different colored capsules containing *Ashwagandha*, *Guduchi* and placebo in the dose of 1 capsule (500 mg) twice a day for 6 months. The parameters such as hemoglobin%, Erythorcyte Sedimentation Rate (ESR), Malondialdehyde (MDA), Super-Oxide Dismutase (SOD) level, etc., were assessed before and after treatment. The Student's t-test was applied to assess significant variations in all of the studied parameters. In this study, there was a significant increase in SOD level and decrease in MDA level in Ashwagandha and Guduchi groups. In conclusion, Ashwagandha and Guduchi may be helpful in preventing the oxidative stress and premature aging.

129. Kulatunga, R., A. R. Dave and M. S. Baghel (2012). "**Clinical efficacy of Guduchyadi Medhya Rasayana on senile memory impairment.**" AYU **33**(2): 202.

Aging has become one of the distinctive demographic phenomena in the 21st century and its social, economic and health implications are the most challenging issues. Senile Memory Impairment is a common condition characterized by mild symptoms of cognitive decline and occurs as a part of the normal aging process. It can be correlated to "Jarajanya Smrtibhramsha" according to Ayurveda. The present study deals with the efficacy of Guduchyadi Medhya Rasayana on Senile Memory Impairment. Granules of Guduchyadi Medhya Rasayana (GMR), which contains Guduchi (***Tinospora cordifolia*** Wild.), Apamarga (*Achyranthes aspera* Linn.), Vidanga (*Embelia ribes* Burm. f.), Shankhapushpi (*Convolvulus pluricaulis* Chois.), Vaca (*Acorus calamus* Linn.), Haritaki (***Terminalia chebula*** Zetz.), Kushtha (*Saussurea lappa* C.B. Clarke), Shatavari (*Asparagus racemosus* Wild.), Cow's ghee and sugar. A total of 138 patients aged in between 55–75 years were registered and randomly divided into two groups as the trial and control groups. The drugs were administered for 3. The trial drug showed memory enhancement, anti-stress, anti-depressant and anxiolytic properties. The trial group showed better results in the management compared to the control group.

130. Kulkarni, R. R., P. S. Patki, V. P. Jog, S. G. Gandage and B. Patwardhan (1991). "**Treatment of osteoarthritis with a herbomineral formulation: A double-blind, placebo-controlled, cross-over study.**" Journal of Ethnopharmacology **33**(1-2): 91-95.

The clinical efficacy of a herbomineral formulation containing roots of ***Withania somnifera***, the stem of *Boswellia serrata*, rhizomes of *Curcuma longa* and a zinc complex (Articulin-F), was evaluated in a randomized, double-blind, placebo controlled, cross-over study in patients with osteoarthritis. After a one-month single blind run-in period, 42 patients with osteoarthritis were randomly allocated to receive either a drug treatment or a matching placebo for a period of three months. After a 15-day wash-out period the patients were transferred to the other treatment for a further period of three months. Clinical efficacy was evaluated every fortnight on the basis of severity of pain, morning stiffness, Ritchie articular index, joint score, disability score and grip strength. Other parameters like erythrocyte sedimentation rate and radiological examination were carried out on a monthly hasis. Treatment

with the herbomineral formulation produced a significant drop in severity of pain (P < 0.001) and disabilitys core (P < 0.05). Radiological assessment, however, did not show any significant changes in both the groups. Side effects observed with this formulation did not necessitate withdrawal of treatment.

131. Kulkarni, R. and A. Kumar (2013). "**A randomized controlled trial on the efficacy of medhya rasayana tablet on academic stress and performance in school children.**" Journal of Ayurveda and Holistic Medicine (JAHM) **1**(3): 1-16.

School children and academics are not exempted from stress. In Indian context, especially for high school children, the demands to be placed high, parental pressures, the future career option and time bound targets along with inherent biological variations of adolescence create paramount stress. Such stress can be detrimental if not well managed. Despite of loss of lives consequent upon stress and poor performance, academic stress is less researched. Psychotherapy is the current gold standard. Hence this trial aims to evolve the risk factors, common manifestations and adaptations with the academic stress, remedial measures with herbal medicine. Objective was the ealuation of efficacy and safety of oral administration of Medhya Rasayana (MR) on manifestations of academic stress and to improve the academic performance. Setting and design: Study was carried out in Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital (SDMCA&H), Hassan, Karnataka, South India, from December, 2010- December, 2012. Interventional, single blinded, randomized psychotherapy-placebo controlled efficacy trial. Materials and methods: 164 children of either sex, studying in tenth standard with normal intelligent quotient (IQ), average and above average stress as indicated from the scores on academic anxiety scale (AASC) and Sarason's Test anxiety scale (TASC), consciously willing to participate in the trial were randomized in to three groups (GP)–medhya (M) and medhya with psychotherapy (MP) and control – Placebo with psychotherapy (PP) group. Ingredients of study drug MR tablet are mandooka parni (*Centella asiatica* Linn), guduchi (***Tinospora cordifolia*** (Wild) Miers), yastimadhu (*Glycirrhiza glabra* Linn) and shankhapushpi (*Evolvulus alsinoides* Linn.). M-group received MR, MP-group with MR and psychotherapy while PP-group given placebo with psychotherapy over 3 months. Stress identified by test anxiety and academic anxiety scores, clinical manifestations and performances were evaluated before, after therapy and after exams. Children suffering from chronic systemic illnesses, developmental disorders, psychiatric illness, post traumatic stress disorder and not willing to participate in the trial were excluded. Results: On statistical analysis using paired and unpaired t test, cross tabs and repeated measures ANOVA, study reveals at par efficacy of trial drug with psychotherapy on clinical manifestations (P=0.000), reducing the stress (P=0.000) for both academic and test anxiety) and hence improving the performance (P=0.000). No adverse reactions documented. MR is effective in management of academic stress and improving academic performance in children.

132. Kumar, A. and A. K. Garai (2012). "**A clinical study on Pandu Roga, iron deficiency anemia, with Trikatrayadi Lauha suspension in children.**" Journal of Ayurveda and Integrative Medicine **3**(4): 215-222.

Nutritional iron deficiency is the most common cause of anemia in India. The nearest correlation of iron deficiency anemia (IDA) can be made with Pandu Roga in Ayurveda. As the IDA is a very common prevalent disease in the society and the side effects of oral allopathic iron preparations are very common, therefore to get a better alternative, an Ayurvedic herbomineral medicine, the Trikatrayadi Lauha, was subjected to a clinical trial in children suffering from IDA. Trikatrayadi Lauha suspension is an Ayurvedic herbomineral drug. The trial drug contains herbal drugs like ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***), which is rejuvenative; ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***), which is an appetizer; and Trimada, which is digestive. Herbal ingredients in the trial drug may increase the bioavailability of Mandura bhasma and lauha bhasma which are important contents of the formulation. Aim was evaluation of safety and efficacy of the compound Trikatrayadi Lauha (that also contains *Triphala* and *Trikatu* amon other herbs) suspension in children with IDA. Settings and Design: Randomized, double-blind placebo-controlled clinical study. The study was conducted on 123 children of IDA for a period of 10 weeks. Clinical features and hematological parameters were documented before, during and after treatment. Observations of the study were analyzed and findings were evaluated by using statistical methods (Student's t test).The present study shows that the trial drug Trikatrayadi Lauha suspension is effective to improve clinical features and hematological parameters significantly. The medicine is effective to increase the hemoglobin level 1.94 g/dL (8.52 -10.46 g/dL, P < 0.001) in 5 weeks and 3.33g/dL (8.52 -11.85g/dL, P < 0.001) in 10 weeks. No adverse effect of the trial drug was observed during the study. In conclusions, the results suggest that Trikatrayadi Lauha is significantly effective in the management of IDA in children.

133. Kumar, C. U., V. K. Pokuri and U. Pingali (2015). "**Evaluation of the analgesic activity of standardized aqueous extract of *Terminalia chebula* in healthy human participants using hot air pain model.**" Journal of Clinical and Diagnostic Research **9**(5): FC01-FC04.

Pain affects millions of people worldwide, opioid analgesics have been used for chronic painful conditions. Due to their adverse effects, safer alternatives would be beneficial. ***Terminalia chebula***, with proven analgesic action has been evaluated in the hot air pain model for its analgesic activity. To evaluate analgesic activity and safety of single oral dose of *Terminalia chebula* using hot air pain model in healthy human participants. Setting and Design: Randomized, Double blind, Placebo controlled, Cross over study.Materials and Methods: After taking written informed consent to IEC approved protocol, 12 healthy human participants were randomized to receive either single oral dose of two capsules of *Terminalia chebula* 500 mg each or identical placebo capsules in a double blinded manner. Thermal pain was assessed using hot air analgesiometer, to deliver thermal pain stimulus. Mean Pain Threshold time and Mean Pain Tolerance time measured in seconds at baseline and 180 minutes post drug. A washout period of two weeks was given for cross-over between the two treatments. Results: *Terminalia chebula* significantly increased mean pain threshold and tolerance time compared to baseline and placebo. Mean pain threshold time increased from 34.06±2.63 seconds to 41.00±2.99 seconds ($p<0.001$) and mean pain tolerance time increased from 49.67± 3.72 seconds to 57.30±3.07 seconds ($p<0.001$). The increase in mean percentage change for pain threshold time

is 20.42% (p<0.001) and for pain tolerance time is 17.50% (p<0.001). In the present study, *Terminalia chebula* significantly increased Pain Threshold time and Pain Tolerance time compared to Placebo. Study medications were well tolerated.

134. Kumar, G., A. Srivastava, S. K. Sharma and Y. K. Gupta (2012). "**Safety and efficacy evaluation of Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) in dyslipidemia patients: A pilot prospective cohort clinical study.**" AYU **33**(2): 197.

Cardiovascular disease has multifaceted in which dyslipidemia, inflammation, and immunity play an important role. Arjuna powder and Arogyavardhini Vati used for centuries has potential for combating these factors. Therefore, the objective of this study was to evaluate the safety and efficacy of Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) for dyslipidemia patients. Total of 108 patients were screened at CGHS Ayurvedic Hospital, New Delhi. It has been used for centuries with claimed efficacy and safety in treatment of jaundice, liver disorders, and various skin disorders. Arogyavardhini Vati consists of ***Terminalia chebula*** (Haritaki), ***Terminalia bellirica*** (Bibhitaka), ***Emblica officinalis*** (Amalaki), Asphaltum (Silajatu-Suddha), *Commiphora wightii* (Guggulu Shuddha), *Ricinus communis* (Eranda), *Picrorrhiza kurroa* (Katuka), leaf juice of *Azadirachta indica* (Nimba) and metals including Shuddha Rasa (purified mercury), Shuddha Gandhaka (purified sulfur), Lauha Bhasma (iron compound in ash form), Abhraka Bhasma (mica in ash form), and Tamra Bhasma (copper compounds in ash form). Ninety-six patients satisfied inclusion criteria, and signed informed consent and detailed medical history was recorded. Arjuna powder (5 g, BD) for 3 weeks and then Arogyavardhini Vati (500 mg, BD) for 4 weeks were prescribed to the patients. The primary efficacy endpoint was reduction in serum total cholesterol, LDL, triglycerides, and increased HDL levels. Secondary endpoints included reduction in serum C-Reactive Protein (CRP) and blood glucose levels. Safety assessments included hepatic function (aminotransferase (ALT), aspartate transaminase (AST), alkaline phosphatase (ALP), bilirubin, and β2 microglobulin), renal function (urea and creatinine and NGAL) tests, and urine mercury level. The study was completed by 87 patients. The male and female patients were 65.5% (57/87) and 34.5% (30/87), respectively. There was a significant reduction in total cholesterol, LDL, triglycerides, CRP, and blood glucose. However, raised HDL level was also observed. Safety assessment results showed no significant change in serum ALT, AST, ALP and bilirubin, urea, creatinine β2 microglobulin, and NGAL levels at the end of study as compared to the baseline levels. In conclusion, the results of the present prospective cohort study showed that Ayurvedic treatment (Arjuna powder and Arogyavardhini Vati) is safe and effective for dyslipidemia.

135. Kumar, G., A. Srivastava, S. K. Sharma, T. D. Rao and Y. K. Gupta (2015). "**Efficacy & safety evaluation of Ayurvedic treatment (Ashwagandha powder & Sidh Makardhwaj) in rheumatoid arthritis patients: A pilot prospective study.**" Indian Journal of Medical Research, Supplement **141**(JAN 2015): 100-106.

In the traditional system of medicine in India Ashwagandha powder (***Withania somnifera***) and Sidh Makardhwaj (sublimed product made from pure mercury, sulphur and gold) have been used for the treatment of rheumatoid arthritis. However, safety and efficacy of this treatment have not been evaluated. Therefore, the present study was carried out to evaluate the efficacy and safety of Ayurvedic treatment

(Ashwagandha powder and Sidh Makardhwaj) in patients with rheumatoid arthritis. Methods: One hundred and twenty five patients with joint pain were screened at an Ayurvedic hospital in New Delhi, India. Eighty six patients satisfied inclusion criteria and were included in the study. Detailed medical history and physical examination were recorded. Patients took 5g of Ashwagandha powder twice a day for three weeks with lukewarm water or milk. Sidh Makardhwaj (100 mg) with honey was administered daily for the next four weeks. The follow up of patients was carried out every two weeks. The primary efficacy end point was based on American College of Rheumatology (ACR) 20 response. Secondary end points were ACR50, ACR70 responses, change from baseline in disease activity score (DAS) 28 score and ACR parameters. Safety assessments were hepatic function [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), bilirubin and β2 microglobulin], renal function (urea and creatinine and NGAL) tests and urine mercury level. Results: The study was completed by 90.7 per cent (78/86) patients. Patients with moderate and high disease activity were 57.7 per cent (45/78) and 42.3 per cent (33/78), respectively. All patients were tested positive for rheumatoid factor and increased ESR level. Ashwagandha and Sidh Makardhwaj treatment decreased RA factor. A significant change in post-treatment scores of tender joint counts, swollen joint counts, physician global assessment score, patient global assessment score, pain assessment score, patient self assessed disability index score and ESR level were observed as compared to baseline scores. ACR20 response was observed in 56.4 per cent (44/78) patients (American College of Rheumatology criteria) and moderate response in 39.74 per cent (31/78) patients [European League Against Rheumatism (EULAR) criteria]. Ayurvedic treatment for seven weeks in rheumatoid arthritis patients showed normal kidney and liver function tests. However, increased urinary mercury levels were was observed after treatment. The findings of the present study suggest that this Ayurvedic treatment (Ashwagandha powder and Sidh Makardhwaj) has a potential to be used for the treatment of rheumatoid arthritis. However, due to small sample size, short duration, non randomization and lack of a control group as study limitations, further studies need to be done to confirm these findings.

136. Kumari, M., S. B. Naik, N. S. Rao, S. S. Martande and A. R. Pradeep (2013). "**Clinical efficacy of a herbal dentifrice on dentinal hypersensitivity: A randomized controlled clinical trial.**" Australian Dental Journal **58**(4): 483-490.

Dentinal hypersensitivity is a common problem and there is a growing interest in herbal based formulations for the treatment of oral diseases. This study was conducted to assess the efficacy of a commercially available novel herbal dentifrice in reduction of dentinal hypersensitivity. A total of 73 subjects (38 males and 35 females; aged 25-60 years) were randomly divided into two groups: Group 1-a placebo dentifrice (The Himalaya Drug Company and Group 2-(test group), a commercially available herbal dentifrice (Hi Ora K, The Himalaya Drug Company Research and Development, Makali, Bangalore) containing ***Triphala*** (***Emblica officinalis*****,** ***Terminalia chebula*****,** ***Terminalia bellirica***) and ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) among other ingredients. Sensitivity scores for controlled air stimulus and cold water were recorded at baseline, 6 weeks and 12 weeks. The test group was found to be significantly better compared to the placebo group at the end of 6 and 12 weeks in reduction of dentinal hypersensitivity. The

novel herbal dentifrice can be recommended for treatment of dentinal hypersensitivity.

137. Kumari, M., S. B. Naik, S. S. Martande, A. R. Pradeep and P. Singh (2014). "**Comparative efficacy of a herbal and a non-herbal dentifrice on dentinal hypersensitivity: a randomized, controlled clinical trial.**" Journal of Investigative and Clinical Dentistry: DOI: 10.1111/jicd.12133.

Dentinal hypersensitivity (DH) is a common painful condition of the teeth of adults. The present study was conducted to assess and compare the efficacy of a commercially-available novel herbal dentifrice with a non-herbal potassium nitrate in the reduction of DH. A total of 145 individuals (73 males and 72 females; aged 25–60 years) were divided into three groups randomly: (a) group 1: a placebo dentifrice; (b) group 2: a commercially-available herbal dentifrice; and (c) group 3: 5% non-herbal potassium nitrate. The sensitivity scores for controlled air stimulus and cold water were recorded at baseline, 6 weeks, and 12 weeks. Both groups 2 and 3 were found to be significantly better, as compared to the placebo group at the end of 6 and 12 weeks in the reduction of DH. Group 2 also showed comparable results in the reduction of DH when compared to group 3. The herbal dentifrice containing ***Triphala*** (***Emblica officinalis*, *Terminalia chebula*, *Terminalia bellirica***) and ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) among other ingredients showed comparable results to the non-herbal dentifrice and can be recommended for the treatment of DH.

138. Kundu, P. K. and P. Chatterjee (2010). "**Meta-analysis of *Diabecon* tablets: Efficacy and safety outcomes from 15 clinical trials in Diabetes Mellitus.**" Indian Journal of Clinical Practice **20**(9): 653-659.

Diabecon is a polyherbal formulation, which contain the extracts of *Balsamodendron mukul, Gymnema sylvestre, Pterocarpus marsupium, Glycyrrhiza glabra, Casearia esculenta, Eugenia jambolana, Asparagus racemosus, Boerhaavia diffusa, Sphaeranthus indicus,* ***Tinospora cordifolia****, Swertia chirata, Tribulus terrestris, Phyllanthus amarus, Gmelina arborea, Gossypium herbaceum, Berberis aristata, Aloe vera*, Shilajeet and powders of *Momordica charantia*, ***Piper nigrum****, Ocimum sanctum, Abutilon indicum, Curcuma longa, Rumex maritimus* and ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) as its main constituents. The aim of this meta-analysis was to analyze the efficacy and safety of Diabecon tablets in 435 patients with diabetes mellitus (DM) as reported in 15 published clinical study reports, which also includes two double-blind studies, published between 1993 and 2004. Diabecon tablets were given as two tablets b.i.d or t.i.d for 12-60 weeks. Improvement in various parameters including fasting blood sugar (FBS), postprandial blood sugar (PPBS), glycated hemoglobin, plasma insulin levels as well as protective effects on diabetic complications including hyperlipidemia, microalbuminuria and diabetic retinopathy were evaluated. Changes in various study parameters from baseline values and values at the end of the study were pooled and analyzed cumulatively using paired 't' test. Statistical analysis was carried out using GraphPad Prism software (version 4.03). Of the 435 diabetic individuals, 332 received only Diabecon as therapy, 69 patients received Diabecon in addition to insulin/oral hypoglycemic agents (OHAs), and remaining 34 patients received placebo. Results of these studies indicate significant

beneficial effects in patients given Diabecon tablets. Significant improvements were observed in FBS, PPBS, glycated hemoglobin, plasma insulin, microalbuminuria, etc. Similar results were observed in studies that used Diabecon along with OHA or insulin in OHA-resistant cases. Diabecon treatment also significantly improved lipid profile [total cholesterol, HDL-cholesterol (HDL-c), LDL-cholesterol (LDL-c)] as well as diabetic retinopathy and microalbuminuria. Adverse effects were seen in only two out of 332 patients treated with Diabecon; these were mild in nature and did not necessitate drug withdrawal. The findings of 15 clinical trials with Diabecon clearly indicated the beneficial effects in DM and related complications with additional advantage of long-term safety.

139. Kurian, G. A., V. Manjusha, S. S. Nair, T. Varghese and J. Padikkala (2014). "**Short-term effect of G-400, polyherbal formulation in the management of hyperglycemia and hyperlipidemia conditions in patients with type 2 diabetes mellitus.**" Nutrition **30**(10): 1158-1164.

Salacia oblonga, ***Tinospora cordifolia***, *Emblica offinalis*, *Curcuma longa* and *Gymnema sylvestre* are Ayurvedic medicinal plants reported to lower plasma glucose levels in animal models. As no clinical validations of those extracts for efficacy have been conducted this study evaluated the effect of polyherbal combination in patients with type 2 diabetes mellitus. Authors screened 250 patients enrolled in a diabetes mellitus screening camp held at District Ayurvedic Hospital, Kottayam, Kerala, India. Of these, 89 patients diagnosed with type 2 diabetes mellitus and 50 healthy volunteers of similar age group were included in the study. Patients were treated with a polyherbal combination drug namely G-400 (1000mg/d) for 8wk with a follow-up of 2wk interval. Fasting and postprandial blood glucose levels measured after 8 wk of G-400 treatment in patients were significantly lower. Indeed diabetic rats showed similar protection with G-400 administration. Furthermore, glycosylated hemoglobin, serum total cholesterol, both high- and low-density lipoprotein cholesterol, and triglycerides showed a significant improvement in G-400-administered patients. Toxicologic profile of the drug was assessed by analyzing the enzyme activities of alkaline phosphatase and alanine aminotransferase along with the concentration of blood urea nitrogen and creatinine in blood and found insignificant change compared with control. Short-term supplementation of G-400 not only attenuates the hyperglycemia, but also acts as hypolipidemic agent in patients with diabetes. Further study should be done for the long-term effect of the drug in larger populations.

140. Kusaba, N., A. Takano, T. Kamiya, K. Yamaguchi, K. Takagaki, S. Tamaru and K. Tanaka (2015). "**Effects of *Terminalia bellirica* extract on postprandial serum triglyceride - Randomised, double blind, placebo controlled, crossover study.**" Japanese Pharmacology and Therapeutics **43**(8): 1175-1180.

A double-blind placebo controlled crossover clinical study was conducted on healthy adults volunteers to examine the effects of ***Terminalia bellirica*** extract on elevation of postprandial serum triglyceride. Methods: The subjects were 34 healthy adult volunteers (mean age of 22.1 ±2.0 years). The subjects were randomly divided to three groups and took a high fat meal (41.6 g fat) with test supplement containing 200 mg or 300 mg *Terminalia bellirica* extract (the 200 mg group, the 300 mg group), or a placebo supplement (the control group). Serum triglyceride was measured

before and 2, 3,4, and 6 hours after intake of the high fat meal. Results: Compared to the control group, the 200 mg group and the 300 mg group had significantly lower serum triglyceride at 2 hours after the high fat meal and IAUC of postprandial serum triglyceride (each P< 0.05). These results suggested that the *Terminalia bellirica* extract had inhibitory effect on the elevation of postprandial serum triglyceride.

141. Kushwaha, S., A. Betsy and P. Chawla (2012). "**Effect of Ashwagandha (*Withania somnifera*) root powder supplementation in treatment of hypertension.**" Studies on Ethno-Medicine **6**(2): 111-115.

Ashwagandha (***Withania somnifera***) is widely used in Ayurvedic medicine, and it is one of the ingredients in many formulations to increase energy, improve overall health and longevity, and prevent disease. The main objective of the study was to analyze the efficacy of Ashwagandha root powder with water and with milk in treatment of hypertension. The experiment was conducted on 51 stress-oriented hypertensive subjects in the age group of 40 to 70 years, selected by purposive sampling. Subjects were divided into group I and group II. Supplementation of 2gm of Ashwagandha root powder was given to group I and group II with milk and water respectively in morning. Blood pressure was also recorded over a period of three months. Overall decrease in systolic blood pressure was found though it was non-significant. Further, decrease in systolic blood pressure was significant in group I, whereas decrease in diastolic blood pressure was significant in both the groups. Hence, supplementation of Ashwagandha with milk is recommended in treatment of stress- oriented hypertension.

142. Kwak, J. S., J. E. Paek, S. Jeong, J. Kim, J. Y. Kim and O. Kwon (2014). "**Systematic review of the effect of dried ginger powder on improvement of nausea and vomiting associated with early pregnancy or motion sickness.**" Journal of Nutrition and Health **47**(1): 45-50.

Ginger (***Zingiber officinale***) has been widely used as an antiemetic agent. This systematic review was aimed at evaluation of the effect of dried ginger powder supplementation on improvement of nausea and vomiting associated with early pregnancy or motion sickness. Authors searched Pubmed, Cochrane, Science Direct, and KISS (Korean studies Information Service System) using keywords such as ginger or *Zingiber officinale* in combination with nausea, vomiting, motion sickness, or pregnancy, published in March 2013. The strength of the evidence was evaluated on the selected 12 RCTs (randomized controlled trials). Eleven trials including 2,630 subjects showed that supplementation with dried ginger powder resulted in significant improvement of nausea or vomiting related to early pregnancy or motion sickness. Among the nine studies including 809 women in early pregnancy before 20 weeks of gestation, ginger sup-plementation was superior to placebo in five studies (n = 305), and as effective as positive control (vitamin B6 or dimen-hydrinate) in four studies (n = 504). Ginger intake significantly reduced the episodes or severity of vomiting related to motion sickness compared to placebo or showed the same effect as several antiemetic drugs in two studies (n = 1,821). These findings added evidence indicating that ginger powder supplements might improve the symptoms of nausea or vomiting related to early pregnancy or motion sickness without significant adverse events.

143. Lakhan, S. E., C. T. Ford and D. Tepper (2015). "**Zingiberaceae extracts for pain: A systematic review and meta-analysis.**" Nutrition Journal **14**(1): 50. doi:10.1186/s12937-015-0038-8.

Members of the family Zingiberaceae including turmeric, ginger (***Zingiber officinale***), Javanese ginger, and galangal have been used for centuries in traditional medicine. Preclinical studies of Zingiberaceae extracts have shown analgesic properties. This study aims to systematically review and meta-analyze whether extracts from Zingiberaceae are clinically effective hypoalgesic agents. Literature was screened from electronic databases using the key words Zingiberaceae AND pain OR visual analogue score (VAS) to identify randomized trials. From this search, 18 studies were identified, and of these, 8 randomized, double-blinded, placebo-controlled trials were found that measured pain by VAS for inclusion in the meta-analysis. Findings indicated significant efficacy of Zingiberaceae extracts in reducing subjective chronic pain (SMD - 0.67; 95 % CI - 1.13 to - 0.21; P = 0.004). A linear dose-effect relationship was apparent between studies (R2 = 0.71). All studies included in the systematic review reported a good safety profile for extracts, without the renal risks associated with non-steroidal anti-inflammatory drugs, and with similar effectiveness. These findings indicated that Zingiberaceae extracts are clinically effective hypoalgesic agents and the available data show a better safety profile than non-steroidal anti-inflammatory drugs. However, **both non-steroidal anti-inflammatory drugs and Zingiberaceae have been associated with a heightened bleeding risk, and there have been no comparator trials of this risk**. Further clinical studies are recommended to identify the most effective type of Zingiberaceae extract and rigorously compare safety, including bleeding risk.

144. Lalla, J. K., S. Y. Nandedkar, M. H. Paranjape and N. B. Talreja (2001). "**Clinical trials of ayurvedic formulations in the treatment of acne vulgaris.**" Journal of Ethnopharmacology **78**(1): 99-102.

Oral and externally used dermatological preparation for acne vulgaris employing herbal extracts have been developed and standardized, the herbal extracts used here were of the plants described in ayurvedic treatise like Bhavprakasha Nighantu and Charak Samhita. The efficacy of the treatment using the oral formulation with or without external preparation has been assessed through conduct of Phase II clinical trials in 53 patients for 4 weeks in a randomized, double-blind, placebo-controlled fashion and following Good Clinical Practices guidelines. The results were statistically analyzed and indicated that combination of use of internal and external preparation showed better efficacy as compared to the use of oral formulation alone. Drug terms used in the study include *Aloe barbadensis* extract; *Azadirachta indica* extract; *Curcuma longa* extract; *Hemidesmus indicus* extract; *Terminalia arjuna* extract; ***Terminalia chebula*** extract; and ***Withania somnifera*** extract.

145. Lawson, M. L., B. Pham, T. P. Klassen and D. Moher (2005). "**Systematic reviews involving complementary and alternative medicine interventions had higher quality of reporting than conventional medicine reviews.**" Journal of Clinical Epidemiology **58**(8): 777-784.

Objective was to compare the quality of systematic reviews reported in English and in languages other than English, and to determine whether there are differences between conventional medicine (CM) and complementary and alternative medicine (CAM) reports. In the study design and setting, authors used the Oxman and Guyatt (OG) scale to assess the quality of reporting in 130 systematic reviews: 50 were language-restricted, 32 were language-inclusive but only English-language (EL) trials contained (inclusive–EL), and 48 were language-inclusive and included trials published in languages other than English (inclusive–LOE). Of the 130 reviews, 105 addressed CM interventions and 25 addressed CAM interventions. Results suggest that comparison of the systematic reviews showed that the quality of reporting and reporting characteristics are not affected by inclusion or exclusion of LOE; however, the quality of reporting of systematic reviews involving CAM interventions is higher than that of reviews focusing on CM interventions. Conclusion is that informal comparison of the OG scale with the data collected on quality assessments showed that the OG scale performs well overall but may not identify important differences in comprehensiveness of the search strategy and avoidance of bias in study selection. Further research is required to determine the best methods for assessing quality of systematic reviews and whether the effect of language restrictions is dependent on the type of intervention (CM or CAM).

146. Laxminarayana Bairy, K., Y. Rao and K. Balachander Kumar (2004). "**Efficacy of *Tinospora cordifolia* on learning and memory in healthy volunteers: A double-blind, randomized, placebo controlled study.**" Iranian Journal of Pharmacology & Therapeutics **3**: 57-60.

Tinospora cordifolia, an Indian medicinal plant, has been reported to have beneficial effects on disorders like peptic ulcer, hepatobiliary disorders, rheumatism, infectious diseases etc. It enhances cognition in normal rats and successfully overcomes cyclosporine induced memory deficit. Methods: Thirty healthy volunteers of age 18-30 years received *Tinospora cordifolia* (500 mg of pure aqueous extract) or a matching placebo for 21 days in a double blind, randomized and placebo controlled design. Learning and memory was assessed by subjecting the volunteers to a battery of psychological tests that aimed at studying visual memory, logical memory, verbal memory, attention span and concentration. *Tinospora cordifolia* showed a significant ($p < 0.05$) increase in the test scores for 'verbal learning and memory' (control - 1.2±1.9, drug 6.9±2.5) and 'logical memory' (control 5.1±6.1, drug 26.6±6.7). No significant untoward effects were reported during *Tinospora cordifolia* treatment. *Tinospora cordifolia*, 500 mg daily, enhances verbal learning and memory and logical memory (of immediate and short term type) compared to placebo in healthy volunteers.

147. Leach, M. J. and S. Kumar (2008). "**The clinical effectiveness of Ginger (*Zingiber officinale*) in adults with osteoarthritis.**" International Journal of Evidence-Based Healthcare **6**(3): 311-320.

International, EMBASE, Health Source Nursing/Academic edition, International Pharmaceutical Abstract, MEDLINE, Natural medicines comprehensive database and TRIP were used. Review methods: Randomised controlled trials or clinical controlled trials were sought, which evaluated the effectiveness of mono-preparations of ginger

(***Zingiber officinale***) in adults with OA of the knee or hip. Critical appraisal of study quality was undertaken using Joanna Briggs Institute critical appraisal instruments. Data extraction was via the Joanna Briggs Institute standard data extraction form for evidence of effectiveness. Results: Five randomised controlled trials were identified from the search, of which three met the inclusion criteria. The methodological quality of the included studies was good. However, given that studies were clinically and methodologically heterogeneous, meta-analysis could not be conducted. Instead, evidence was summarised in narrative form. For changes in pain severity, studies comparing ginger extract (n = 110) to placebo (n = 111) reported mixed findings in support of the use of Ginger. Studies comparing ginger to an active control found participants who received Ibuprofen (n = 96) had a greater change in median pain intensity compared with participants who received Ginger (n = 110), and while findings were statistically significant for only one of the two studies, the results had limited clinical significance. Similarly, while two placebo-controlled studies reported differences between ginger (n = 70) and placebo (n = 71) for changes in disability and functional capacity, the difference was statistically and clinically significant for only one study. In one study comparing ginger to an active control, participants receiving Ibuprofen (n = 56) reported a statistically significant improvement in disability and functional capacity over timewhen compared with participants receiving Ginger (n = 56). In terms of safety, Ginger was well tolerated when compared with Ibuprofen, with infrequent reports of mild, and predominantly gastrointestinal, adverse effects. Current evidence is weak for the use of Ginger in adults with OA of the knee and/or hip. Much of this can be attributed to significant heterogeneity between studies. Improvements in research design, instrumentation and ginger dosage, which more closely reflect current clinical practice, may help to demonstrate the safe and effective use of Ginger in OA sufferers.

148. Lee, J. and H. Oh (2013). "**Ginger as an antiemetic modality for chemotherapy-induced nausea and vomiting: a systematic review and meta-analysis.**" Oncology nursing forum **40**(2): 163-170.

Objective was to evaluate the effect of ginger (***Zingiber officinale***) as an antiemetic modality for the control of chemotherapy-induced nausea and vomiting (CINV). Databases searched included MEDLINE® (PubMed), Embase, CINAHL®, Cochrane Central Register of Controlled Trials, Korean Studies Information Service System, Research Information Sharing Service by the Korean Education and Research Information Service, and Dissertation Central. A systematic review was conducted of five randomized, controlled trials involving 872 patients with cancer. Ginger was compared with placebo or metoclopramide. The participant characteristics, chemotherapy regimen and antiemetic control, ginger preparation and protocol, measurements, results of the studies, adherence to the treatment protocol, and side effects were reviewed systematically. The incidence and severity of acute and delayed CINV were subject to meta-analysis. The incidence of acute nausea ($p = 0.67$), incidence of acute vomiting ($p = 0.37$), and severity of acute nausea ($p = 0.12$) did not differ significantly between the ginger and control groups. Current evidence does not support the use of ginger for the control of CINV. Ginger did not contribute to control of the incidence of acute nausea and vomiting or of the severity of acute nausea. Ginger has long been regarded as a traditional antiemetic modality, but its

effectiveness remains to be established. The findings of this study could be incorporated into clinical guidelines, such as the Oncology Nursing Society's Putting Evidence Into Practice resources. Current evidence supports the need for more methodologically rigorous studies in this area. Although ginger is known as a traditional antiemetic, current evidence does not support the effect of ginger in CINV control. The findings of this study inform healthcare providers that its effectiveness remains to be established from methodologically rigorous future trials.

149. Lekurwale, P., K. Pandey and P. Yadaiah (2010). "**Management of Amavata with 'Amrita Ghrita': A clinical study.**" AYU **31**(4): 430.

Amavata is a disease caused due to the vitiation or aggravation of Vayu associated with Ama. Vitiated Vayu circulates the Ama all over the body through Dhamanies, takes shelter in the Shleshma Sthana (Amashaya, Sandhi, etc.), producing symptoms such as stiffness, swelling, and tenderness in small and big joints, making a person lame. The symptoms of Amavata are identical to rheumatism, which include rheumatoid arthritis and rheumatic fever. It is observed that rheumatism is an autoimmune disorder, which is among the collagen disorders having strong and significant parlance with Amavata. Various drug trials were already carried out on Amavata, yet there is a lacuna in the management of Amavata. Hence, in the present clinical study, 28 patients were selected and kept on 'Amrita Ghrita'. Preparation of Amrita Ghrita: Before the preparation, Murchhana of Ghrita10 was done with Amalaki (***Emblica officinalis***), Bibhitaki (***Terminalia bellirica***), Haritaki (***Terminalia chebula***), Nagarmotha (*Cyperus rotundus*), Haridra (*Curcuma longa*), and Nimbu ras (*Citrus media*). Amrita Ghrita was prepared in the college pharmacy with the following ingredients: Ghrita (Murchhita) 10 kg, Shunthi kalka (***Zingiber officinale***) 1 kg 660 g, Guduchi quath (***Tinospora cordifolia***) 40 lit. All the patients were investigated for complete blood count (CBC), rheumatoid arthritis (RA) titer, Antistreptolysin O (ASO) titer, C-reactive protein (CRP) titer, platelet count, urine routine, and microscopic, before and after treatment. The collected data was distributed according to age, sex, and prakruti, and a t-test was applied for the clinical assessment of the subjective and objective parameters of 'Amrita Ghrita,' and it has shown significant reduction in the positivity of the RA titer ($t > 5.09$, at the 0.001% level), ASO titer ($t > 4.08$, at the 0.001% level), and CRP titer ($t > 4.82$, at the 0.001% level), and weight gain ($t > 5.12$, at the 0.001% level), as also an increase in Hb% ($t > 9.22$, at the 0.001% level), and platelet count ($t > 5.90$, at the 0.001% level), and decrease in ESR ($t > 9.70$, at the 0.001% level).

150. Li, Y., V. H. Tran, C. C. Duke and B. D. Roufogalis (2012). "**Preventive and protective properties of *Zingiber officinale* (Ginger) in diabetes mellitus, diabetic complications, and associated lipid and other metabolic disorders: A brief review.**" Evidence-based Complementary and Alternative Medicine **2012**. Article number 516870.

Zingiber officinale (ginger) has been used as herbal medicine to treat various ailments worldwide since antiquity. Recent evidence revealed the potential of ginger for treatment of diabetes mellitus. Data from in vitro, in vivo, and clinical trials has demonstrated the antihyperglycaemic effect of ginger. The mechanisms underlying these actions are associated with insulin release and action, and improved carbohydrate and lipid metabolism. The most active ingredients in ginger are the

pungent principles, gingerols, and shogaol. Ginger has shown prominent protective effects on diabetic liver, kidney, eye, and neural system complications. The pharmacokinetics, bioavailability, and the safety issues of ginger are also discussed in this update.

151. Londhe, P. (2015). "**Udaraprashamanartha Amalakyadi Kwatha in Alcoholic Liver Disease.**" International Journal of Ayurvedic Medicine **6**(1): 115-121.

Alcoholic liver disease is a term that encompasses the hepatic manifestations of alcohol overconsumption, including fatty liver, alcoholic hepatitis, and chronic hepatitis with hepatic fibrosis or cirrhosis. Alcoholic liver disease (ALD) is the most prevalent cause of advanced liver disease. However, there has been limited research investment into ALD despite its significant burden on the health. Many patients of ALD having the clinical manifestations viz.ascites, hepatitis etc. used to visit the OPD of Dr. M.N. Agashe hospital, Satara.Hence, being an Ayurvedic hospital it was decided to work upon ALD with some Ayurvedic medicines. For that total 30 patients of ALD were selected and treated with 'AmalakyadiKwatha' (containing Amalaki (***Emblica officinalis***), Haritaki (***Terminalia chebula***) and Guduchi (***Tinospora cordifolia***) and Katuki (*Piccrorhiza kurroa*) in equal proportion. The formulation was given in the dose of 20 ml twice a day for the duration of one month. All the necessary parameters along with required investigations were assessed. In the results, weight of the patients was reduced by 12.13%. The parameters like abdominal girth (7.13 %↓), distance between umbilicus and xiphisternum (17.34 %↓), distance between umbilicus and pubis (19.18 %↓), distance between umbilicus and right anterior superior iliac crest (19.55 %↓), distance between umbilicus and left anterior superior iliac crest (16.83 %↓) showed highly significant results. The biochemical parameters such as Bilirubin, SGPT and SGOT also showed significant reduction in their levels. Hence, it can be said that Aamlakyadi kwath can be a good option for disease like ALD instead of repeated abdominal paracentesis.

152. Lone, A. H., T. Ahmad and A. H. Naiyar (2011). "**Clinical evaluation of efficacy of *Majoon Ushba* and *Roghane Hindi* in the management of psoriasis: A randomized single-blind, placebo-controlled study.**" Journal of Ayurveda and Integrative Medicine **2**(1): 26-31.

Psoriasis is a common dermatological disease affecting up to 1-2% of the world's population. It is associated with both organic and psychosocial complications like psoriatic arthropathy, nephritis, infection, hyperuricemia, hypoproteinemia, depression, and stress, and is responsible for hindering patients' daily activities. The present study was conducted to assess the safety and efficacy of two pharmacopeial Unani formulations (Majoon Ushba and Roghane Hindi) in the management of psoriasis on scientific parameters. Composition of *Majoon Ushba* contains many herbs including Post balela (***Terminalia bellirica***), Halela siyah (***Terminalia chebula***), Post halela zard (***Terminalia chebula***). Composition of *Roghane Hindi* includes among others Halela siyah (*Terminalia bellirica*). Thirty diagnosed psoriasis patients, satisfying the inclusion criteria, were selected for a randomized, single-blind, placebo-controlled study in the Department of Moalajat (Medicine), National Institute of Unani Medicine, Bangalore. The patients were divided by the method of Random Table Numbers into test and control groups after obtaining informed consent. The

experimental group comprised 20 patients to whom Majoon Ushba 5 g was administered orally twice daily and Roghane Hindi was applied locally twice daily. The control group comprised 10 patients who were given placebo drugs orally and topically. The duration of the trial was 8 weeks and follow-up was done fortnightly. The severity of psoriasis and efficacy of the drug was assessed by the Psoriasis Area and Severity Index (PASI) Scale. The results of both groups were compared and analyzed statistically. The study showed significant reduction in the PASI score in the test group ($P < 0.01$) as compared to placebo. No obnoxious side effects were observed in the test group: toxicological parameters were within normal limits even after 2 months of treatment. It was therefore concluded that Majoon Ushba and Roghane Hindi are safe and effective in the management of psoriasis.

153. Lua, P. L., N. Salihah and N. Mazlan (2015). "**Effects of inhaled ginger aromatherapy on chemotherapy-induced nausea and vomiting and health-related quality of life in women with breast cancer.**" Complementary Therapies in Medicine **23**(3): 396-404.

Objective was to assess the efficacy of inhaled ginger (***Zingiber officinale***) aromatherapy on nausea, vomiting and health-related quality of life (HRQoL) in chemotherapy breast cancer patients. Design was single-blind, controlled, randomized cross-over study. Patients received 5-day aromatherapy treatment using either ginger essential oil or fragrance-matched artificial placebo (ginger fragrance oil) which was instilled in a necklace in an order dictated by the treatment group sequence. Setting: Two oncology clinics in the East Coast of Peninsular Malaysia. Main outcome measures considered were VAS nausea score, frequency of vomiting and HRQoL profile (EORTC QLQ-C30 scores). Sixty female patients completed the study (age = 47.3 ± 9.26 years; Malay = 98.3%; on highly emetogenic chemotherapy = 86.7%). The VAS nausea score was significantly lower after ginger essential oil inhalation compared to placebo during acute phase ($p = 0.040$) but not sustained for overall treatment effect (treatment effect: $F = 1.82$, $p = 0.183$; time effect: $F = 43.98$, $P < 0.001$; treatment × time effect: $F = 2.04$; $p = 0.102$). Similarly, there was no significant effect of aromatherapy on vomiting [$F(1, 58) = 0.29$, $p = 0.594$]. However, a statistically significant change from baseline for global health status ($P < 0.001$) was detected after ginger essential oil inhalation. A clinically relevant 10 points improvement on role functioning ($p = 0.002$) and appetite loss ($P < 0.001$) were also documented while patients were on ginger essential oil. Conclusion is that the evidence derived from this study is not sufficiently convincing that inhaled ginger aromatherapy is an effective complementary therapy for CINV. The findings for HRQoL were however encouraging with significant improvement in several domains.

154. Maenthaisong, R., N. Chaiyakunapruk, W. Tiyaboonchai, A. Tawatsin, A. Rojanawiwat and U. Thavara (2014). "**Efficacy and safety of topical *Trikatu* preparation in, relieving mosquito bite reactions: A randomized controlled trial.**" Complementary Therapies in Medicine **22**(1): 34-39.

Trikatu is composed of dried fruits of ***Piper nigrum*** L and ***Piper retrofractum*** Vahl, and dried rhizomes of ***Zingiber officinale*** R (*Note*: it should be ***Zingiber officinale, Piper longum, Piper nigrum***). Although this preparation has been used to relieve pruritis, pain, and inflammation for a long time, there is no clinical evidence to confirm its efficacy and safety. Therefore, authors performed a double-blind, within

person-randomized controlled study of 30 healthy volunteers to determine efficacy and safety of topical *Trikatu* on mosquito bite reactions. Methods: All subjects were bitten by Aedes aegypti laboratory mosquitoes on their forearms and they were randomly assigned arms to apply either *Trikatu* or reference product on the mosquito bite papule. The main outcome was the difference of papule size reduction at 30. min, measured by a caliper, between the *Trikatu* and reference arms. Pruritis, redness, pain, and patient satisfaction were assessed at 15, 30, 60, 180, and 360. min as secondary outcomes. Results: There were no significant differences between treatment and reference arms on any outcome at any time of measurement. *Trikatu* did not show additional effects for relieving mosquito bite reaction as compared with the reference product containing camphor, menthol, and eucalyptus. For further study, it is very important to consider a proper selection of subjects, comparator product, and concentration of extract when *Trikatu* preparation is investigated.

155. Maghbooli, M., F. Golipour, A. Moghimi Esfandabadi and M. Yousefi (2014). "**Comparison between the efficacy of ginger and sumatriptan in the ablative treatment of the common migraine.**" Phytotherapy Research **28**(3): 412-415.

Frequency and torment caused by migraines direct patients toward a variety of remedies. Few studies to date have proposed ginger (***Zingiber officinale***) derivates for migraine relief. This study aims to evaluate the efficacy of ginger in the ablation of common migraine attack in comparison to sumatriptan therapy. In this double-blinded randomized clinical trial, 100 patients who had acute migraine without aura were randomly allocated to receive either ginger powder or sumatriptan. Time of headache onset, its severity, time interval from headache beginning to taking drug and patient self-estimation about response for five subsequent migraine attacks were recorded by patients. Patients, satisfaction from treatment efficacy and their willingness to continue it was also evaluated after 1 month following intervention. Two hours after using either drug, mean headaches severity decreased significantly. Efficacy of ginger powder and sumatriptan was similar. Clinical adverse effects of ginger powder were less than sumatriptan. Patients' satisfaction and willingness to continue did not differ. The effectiveness of ginger powder in the treatment of common migraine attacks is statistically comparable to sumatriptan. Ginger also poses a better side effect profile than sumatriptan.

156. Mahdi, A. A., K. K. Shukla, M. K. Ahmad, S. Rajender, S. N. Shankhwar, V. Singh and D. Dalela (2011). "***Withania somnifera* improves semen quality in stress-related male fertility.**" Evidence-based Complementary and Alternative Medicine **2011**. Article ID 576962

Stress has been reported to be a causative factor for male infertility. ***Withania somnifera*** has been documented in Ayurveda and Unani medicine system for its stress-combating properties. However, limited scientific literature is available on this aspect of *W. somnifera*. Authors undertook the present study to understand the role of stress in male infertility, and to test the ability of W. somnifera to combat stress and treat male infertility. They selected normozoospermic but infertile individuals (N = 60), further categorized in three groups: normozoospermic heavy smokers (N = 20), normozoospermics under psychological stress (N = 20) and normozoospermics with infertility of unknown etiology (N = 20). Normozoospermic fertile men (N = 60) were recruited as controls. The subjects were given root powder of *W. somnifera* at a rate

of 5 g/day for 3 months. Measuring various biochemical and stress parameters before and after treatment, suggested a definite role of stress in male infertility and the ability of *W. somnifera* to treat stress-related infertility. Treatment resulted in a decrease in stress, improved the level of anti-oxidants and improved overall semen quality in a significant number of individuals. The treatment resulted in pregnancy in the partners of 14% of the patients.

157. Mahajan, S., P. Chauhan, S. K. Subramani, A. Anand, D. Borole, H. Goswamy and G. B. K. S. Prasad (2015). "**Evaluation of "GSPF kwath": A *Gymnema sylvestre*-containing polyherbal formulation for the treatment of human type 2 diabetes mellitus.**" European Journal of Integrative Medicine **7**(3): 303-311.

Since ancient times, plant-based herbal formulations have been used in Indian traditional medicine to treat diabetes. This observational study investigated the antihyperglycemic, antihyperlipidemic, and antioxidant potential of a Gymnema sylvestre polyherbal formulation ("GSPF kwath") in patients with type 2 diabetes mellitus. A before-and-after study of 32 human subjects with type 2 diabetes mellitus was carried out. Patients were administered "GSPF kwath" consisting of a mixture of 10 herbs: G. sylvestre (gurmar), Syzygium cumini (jamun seed), ***Phyllanthus emblica*** (amla), Curcuma longa (haldi), Pterocarpus marsupium (vijaysaar), ***Terminalia chebula*** (harad), Cassia fistula (amaltas), Picrorhiza kurroa (kutki), Swertia chirata (chirayita), and ***Terminalia bellirica*** (behada). Patients were administered 50 ml of aqueous extract derived from 10 g of "GSPF kwath" daily on an empty stomach for 6 months. The blood glucose levels were monitored monthly, and glycosylated hemoglobin, lipid profile and biomarkers of oxidative stress, and liver and kidney function markers were measured at 3-monthly intervals. Daily administration of "GSPF kwath" regularly for 6 months resulted in significant reductions of blood glucose and glycosylated hemoglobin levels. There was also a significant increase in high-density lipoprotein cholesterol levels and concomitant decreases in total cholesterol, triglyceride, low-density lipoprotein cholesterol, and very-low-density lipoprotein levels. Patients exhibited a significant improvement in the biochemical markers for oxidative stress. The results suggest that the polyherbal formulation GSPF may have the potential to regulate both hyperglycemia and possibly hyperlipidemia. "GSPF kwath" may be a potentially safe and effective therapy for the treatment of type 2 diabetes mellitus.

158. Mahalwar, V., K. B. Mahapatra and S. P. Otta (2012). "**Management of artavakshaya (hypomenorrhoea) with obesity by a herbal compound.**" International Journal of Research in Ayurveda and Pharmacy **3**(6): 847-851.

Obesity per se represents a condition of sex hormone imbalance in women. Obesity is associated with three biochemical alterations that affect normal ovulation e.g. 1. Hyperinsulinaemia 2. Increased peripheral conversion of androgen to estrogen and 3. Decrease level of sex hormone binding globulin (SHBG) resulting in increased level of free oestradiol and testosterone. Level of sex hormone binding protein (SHBG) tends to linearly decrease with increasing body fat and this may lead to an increased fraction of free androgens and thus estrogen level decreases. SHBG levels are regulated by a complex of factor including estrogen, iodothyronies and growth hormone as stimulating agents and androgens and insulin as inhibiting factor. The

net balance of this regulation with the dominant role of insulin which inhibits SHBG synthesis in the liver may be responsible for the decrease of SHBG concentration observed in obesity. Fat represent a site of intensive sex hormone metabolism and interconversion due to the presence of several steroidaogenetic enzymes such as 3 beta dehydrogenese, 17 beta hydroxydehydrogenase and the aromatase systems. Obesity may thus add further specific mechanism in the development of androgen excess in women and decreases oestrogen. The present clinical study was planned to assess the efficacy of an indigenous compound in sthoulya janya artavakshaya, which contains Sunthi (***Zingiber officinale***), Pippali (***Piper longum***), Maricha (***Piper nigrum***), Vidanga, Tvak, Guggullu, Gomutra in equal quantity and was made vati and given in the doses of 1 gm three times a day with luke warm water. The effect of indigenous compound as evident in the clinical trial was recorded along with detailed data pertaining to the case history.

159. Mahluji, S., V. E. Attari, M. Mobasseri, L. Payahoo, A. Ostadrahimi and S. E. Golzari (2013). "**Effects of ginger (*Zingiber officinale*) on plasma glucose level, HbA1c and insulin sensitivity in type 2 diabetic patients.**" International Journal of Food Sciences and Nutrition **64**(6): 682-686.

The present study was aimed to evaluate the effects of ***Zingiber officinale*** on some biochemical parameters in type 2 diabetic (DM2) patients. In a randomized double-blind placebo controlled trial, 64 patients with DM2 were assigned to ginger or placebo groups (receiving 2 g/d of each). A 3 d diet record, anthropometric measurements and concentrations of fasting blood glucose (FPG), HbA1c, lipid profile (including total cholesterol, triglyceride, low density lipoprotein and high density lipoprotein) and also the homeostasis model assessment (HOMA) and quantitative insulin-sensitivity check index (QUICKI) were determined before and after 2 months of intervention. Ginger supplementation significantly lowered the levels of insulin (11.0 ± 2.3 versus 12.1 ± 3.3; p = 0.001), LDL-C (67.8 ± 27.2 versus 89.2 ± 24.9; p = 0.04), TG (127.7 ± 43.7 versus 128.2 ± 37.7; p = 0.03) and the HOMA index (3.9 ± 1.09 versus 4.5 ± 1.8; p = 0.002) and increased the QUICKI index (0.313 ± 0.012 versus 0.308 ± 0.012; p = 0.005) in comparison to the control group; while, there were no significant changes in FPG, TC, HDL-C and HbA1c (p > 0.05). In summary, ginger supplementation improved insulin sensitivity and some fractions of lipid profile in DM2 patients. Therefore it may be considered as a useful remedy to reduce the secondary complications of DM2.

160. Mahluji, S., A. Ostadrahimi, M. Mobasseri, V. E. Attari and L. Payahoo (2013). "**Anti-inflammatory effects of *Zingiber officinale* in type 2 diabetic patients.**" Advanced Pharmaceutical Bulletin **3**(2): 273-276.

Low-grade inflammation, a common feature in type 2 diabetes (DM2), causes some chronic complications in these patients. The present study was aimed to evaluate the effects of ginger (***Zingiber officinale***) on pro-inflammatory cytokines (IL-6 and TNF-α) and the acute phase protein hs-CRP in DM2 patients as a randomized double-blind placebo controlled trial. A total of 64 DM2 patients randomly were assigned to ginger or placebo groups and received 2 tablets/day of each for 2 months. The concentrations of IL-6, TNF-α and hs-CRP in blood samples were analyzed before and after the intervention. Ginger supplementation significantly reduced the levels of

TNF-α (P = 0.006), IL-6 (P = 0.02) and hs-CRP (P = 0.012) in ginger group in comparison to baseline. Moreover, the analysis of covariance showed that the group received ginger supplementation significantly lowered TNF- a (15.3 ± 4.6 vs. 19.6 ± 5.2; P = 0.005) and hs-CRP (2.42 ± 1.7 vs. 2.56 ± 2.18; P = .016) concentrations in comparison to control group. While there were no significant changes in IL-6 (7.9 ± 2.1 vs. 7.8 ± 2.9; P > .05). In conclusion, ginger supplementation in oral administration reduced inflammation in type 2 diabetic patients. So it may be a good remedy to diminish the risk of some chronic complications of diabetes.

161. Malhotra, R., V. Grover, A. Kapoor and D. Saxena (2011). "**Comparison of the effectiveness of a commercially available herbal mouthrinse with chlorhexidine gluconate at the clinical and patient level.**" Journal of Indian Society of Periodontology **15**(4): 349-352.

The key to good oral health is hidden in nature. Natural herbs like neem, tulsi, pudina, clove oil, ajwain, ***Triphala*** (***Emblica officinalis*****,** ***Terminalia chebula*****,** ***Terminalia bellirica***) and many more has been used since ages either as a whole single herb or as a combination against various oral health problems like bleeding gums, halitosis, mouth ulcers and preventing tooth decay. The aim of the study was to compare the efficacy of a commercially available herbal mouthrinse (Herboral) with that of chlorhexidine gluconate which is considered to be a gold standard as an anti-plaque agent. Materials and Methods: A randomized, two-group, parallel study as a 'de novo' plaque accumulation model was carried out on 50 subjects (23 males and 27 females). At baseline, all participants received a professional prophylaxis and were randomly assigned to the test (Herbal mouthrinse) and control (Chlorhexidine Gluconate) group. On the following three days, all subjects rinsed with 10 ml of the allocated mouthrinse twice daily for 1 min. They were asked to refrain from use of any other oral hygiene measures during the study. At the end of the experimental period, plaque was assessed and a questionnaire was filled by all subjects. Results: Chlorhexidine (mean plaque score=1.65) inhibited plaque growth significantly more than the herbal mouthrinse (mean plaque score=1.43, P<0.001). The results of the questionnaire showed that Herboral was preferred by patients for its taste, its convenience of use and taste duration (aftertaste). However, Chlorhexidine was considered to be more effective in reducing plaque as compared to Herboral. Herbal mouthrinse was found to be a potent plaque inhibitor, though less effective than Chlorhexidine Gluconate. However, it can serve as a good alternative for the patients with special needs as in case of diabetics, xerostomics, and so on.

162. Mamidi, P., K. Gupta and A. B. Thakar (2014). "**Ashwagandha in psychogenic erectile dysfunction: Ancillary findings.**" International Journal of Research in Ayurveda and Pharmacy **5**(1): 36-40.

Erectile dysfunction has been defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. The present study was based on the ancillary findings of the main study (which was based on scoring of International Index of Erectile Function -IIEF) in Psychogenic Erectile Dysfunction (PED). The study main findings based on IIEF scoring reported, 12.6 % improvement in trial group (Ashwagandha -***Withania somnifera***) and 19.11 % improvement in control group (Placebo) (P < 0.001). Ashwagandha didn't provide relief in PED on IIEF

scoring. The present ancillary findings are based on the measurement tools like, Erectile Dysfunction Severity Index (EDSI), Quality of Erections Questionnaire (QEQ) and Quality of Internet Mental Health Quality of Life scale (IMHQOL) on same sample, with same materials and methods and intervention as of the main study. The aim of this study is to evaluate the efficacy of Ashwagandha on EDSI, QEQ and IMHQOL. Two assessments were done before and after treatment, based on the scorings of EDSI, QEQ and IMHQOL. Paired and unpaired't' test were used for statistical analysis. In trial group (n = 41), 10.52 % improvement on EDSI, 4.18 % on IMHQOL and 39.22 % on QEQ and in control group (n = 45), 11.20 % of improvement on EDSI, 5.95 % on IMHQOL and 45.74 % on QEQ was observed (P < 0.001). No statistically significant difference (P > 0.05) found in between the two groups on all the scales. Ashwagandha did not prove better than placebo on EDSI, QEQ and IMHQOL scales.

163. Mandal, P., A. Das, S. Majumdar, T. Bhattacharyya, T. Mitra and R. Kundu (2014). "**The efficacy of ginger added to ondansetron for preventing postoperative nausea and vomiting in ambulatory surgery.**" Pharmacognosy Research **6**(1): 52-57.

Post-operative nausea and vomiting (PONV) frequently hampers implementation of ambulatory surgery in spite of so many costly antiemetic drugs and regimens. The study was carried out to compare the efficacy of ginger (***Zingiber officinale***) added to Ondansetron in preventing PONV after ambulatory surgery. It was a prospective, double blinded, and randomized controlled study. From March 2008 to July 2010, 100 adult patients of either sex, aged 20-45, of ASA physical status I and II, scheduled for day care surgery, were randomly allocated into Group A[(n = 50) receiving (IV) Ondansetron (4 mg) and two capsules of placebo] and Group B[(n = 50) receiving IV Ondansetron (4 mg) and two capsules of ginger] simultaneously one hour prior to induction of general anaesthesia (GA) in a double-blind manner. One ginger capsule contains 0.5 gm of ginger powder. Episodes of PONV were noted at 0.5h, 1h, 2h, 4h, 6h, 12h and 18h post- operatively. Statistically significant difference between groups A and B (P < 0.05), was found showing that ginger ondansetron combination was superior to plain Ondansetron as antiemetic regimen for both regarding frequency and severity. Prophylactic administration of ginger and ondansetron significantly reduced the incidence of postoperative nausea and vomiting compared to ondansetron alone in patients undergoing day care surgery under general anaesthesia.

164. Manjunath, N. K. and S. Telles (2005). "**Influence of Yoga & Ayurveda on self-rated sleep in a geriatic population.**" Indian Journal of Medical Research **121**(5): 683-690.

Sleep in older persons is characterized by decreased ability to stay asleep, resulting in fragmented sleep and reduced daytime alertness. Pharmacological treatment of insomnia in older persons is associated with hazardous side effects. Hence, the present study was designed to compare the effects of Yoga and Ayurveda on the self rated sleep in a geriatric population. Of the 120 residents from a home for the aged, 69 were stratified based on age (five-year intervals) and randomly allocated to three groups i.e., Yoga (physical postures, relaxation techniques, voluntarily regulated breathing and lectures on yoga philosophy), Ayurveda (a herbal preparation), and Wait-list control (no intervention). The groups were evaluated for self-assessment of sleep over a one week period at baseline, and after three and six months of the

respective interventions. The Yoga group showed a significant decrease in the time taken to fall asleep (approximate group average decrease: 10 min, P<0.05), an increase in the total number of hours slept (approximate group average increase: 60 min, P< 0.05) and in the feeling of being rested in the morning based on a rating scale (P<0.05) after six months. The other groups showed no significant change. Yoga practice improved different aspects of sleep in a geriatric population.

165. Manohar, P. R. (2012). "**Clinical evidence in the tradition of Ayurveda", In, S. Rastogi (ed.),** ***Evidence-Based Practice in Complementary and Alternative Medicine: Perspectives, Protocols, Problems and Potential in Ayurveda*****.** Springer-Verlag Berlin Heidelberg, pp. 67-78.

A careful study of the classical literature of Ayurveda provides compelling indications to believe that the practice of building clinical evidence was nurtured in the tradition of Ayurveda. Ayurveda exhibits the characteristics of a knowledge system and requires that observations are validated to be accepted as knowledge. The celebrated textbook on general medicine known as the *Charaka Samhita* remarks that the outcome of a clinical intervention is to be dismissed as accidental or due to chance if it cannot be substantiated with proper evidence and reasoning. Classical texts of Ayurveda also discuss about self-limiting diseases and the need to distinguish between the true effect and chance effect of a medical intervention. Classical treatments of Ayurveda are multimodal in nature and cannot be studied using conventional methods of clinical research. Appropriate research designs for both observational studies as well as randomized clinical trials need to be developed for meaningful evaluation of clinical interventions in Ayurveda. This chapter reviews the gaps in the current approaches to clinical research in Ayurveda and highlights the attempts that have been made to develop methodologies that are appropriate not only for Ayurveda but also such other systems of traditional, complementary, or alternative medicine. An elaborate discussion of the classical approach in building clinical evidence in the tradition of Ayurveda will also be attempted in the process.

166. Marx, W. M., L. Teleni, A. L. McCarthy, L. Vitetta, D. McKavanagh, D. Thomson and E. Isenring (2013). "**Ginger (*Zingiber officinale*) and chemotherapy-induced nausea and vomiting: A systematic literature review.**" Nutrition Reviews **71**(4): 245-254.

Chemotherapy-induced nausea and vomiting (CINV) is a common side-effect of cytotoxic treatment. It continues to affect a significant proportion of patients despite the widespread use of antiemetic medication. In traditional medicine, ginger (***Zingiber officinale***) has been used to prevent and treat nausea in many cultures for thousands of years. However, its use has not been confirmed in the chemotherapy context. To determine the potential use of ginger as a prophylactic or treatment for CINV, a systematic literature review was conducted. Reviewed studies comprised randomized controlled trials or crossover trials that investigated the anti-CINV effect of ginger as the sole independent variable in chemotherapy patients. Seven studies met the inclusion criteria. All studies were assessed on methodological quality and their limitations were identified. Studies were mixed in their support of ginger as an anti-CINV treatment in patients receiving chemotherapy, with three demonstrating a positive effect, two in favor but with caveats, and two showing no effect on measures

of CINV. Future studies are required to address the limitations identified before clinical use can be recommended.

167. Mehra, R., R. Makhija and N. Vyas (2011). "**A clinical study on the role of Ksara Vasti and *Triphala* Guggulu in Raktarsha (Bleeding piles).**" AYU **32**(2): 192-195.

Shonitarsha is a common affliction which has been described and treated since the beginning of human civilization. Hemorrhoidal cushions are a part of normal anatomy but become pathological when swollen or inflamed. Treatment of piles in modern medicine is hemorrhoidectomy which results in repeated recurrences. Ayurveda provides a cure and prevents recurrences. Present study was carried out using a combination of Apamarga Kshara Basti and *Triphala*guggulu. The results of the clinical assessment of the indigenous formulation on 129 patients with bleeding piles are reported in this paper; 55 patients of a total of 129 showed marked relief. Ingredients of ***Triphalaguggulu*** tablets were ***Emblica officinalis*** (Amla), ***Terminalia chebula*** (Hareetaki), ***Terminalia bellirica*** (Vibheetaki), ***Piper longum*** (long pepper), and *Commiphora mukul* (Guggulu). ***Triphala*** is well known for its wound-healing quality. It also soothes the inflamed mucous layer and helps in checking the further infection. Guggulu is one of the best known anti-inflammatory herbs of Ayurveda. It also helps in healing the inflammation of fistula-in-ano. *Triphala* helps in easy bowel movements and relieves the constipation, a problem often troubling the people suffering from hemorrhoids. ***Piper longum*** helps in the digestion and assimilation of food nutrients.

168. Mehra, R., M. Prasad and G. Lavekar (2009). "**An approach of Ashwagandha+ Guggulu in Atheromatous CHD associated with Obesity.**" AYU **30**(2): 121-125.

The Coronary Artery Disease or Coronary Heart Disease is the single biggest killer (60%) and the most common cause of maximum morbidity, ironically. Infact this is a disease whose control is most in our hands and it is most life style dependent. In accordance with the latest reports more than 13.7% of the adult population is suffering from coronary heart disease in India, and this figure is constantly on the rise year after year. The main cause of the disease is obesity in terms of enhanced circumference, deposition of cholesterol and fat in the inner smooth lining of the coronary arteries supplying blood to the heart resulting in their blockages and obstruction to blood flow through them. Atheromatous plaque is formed which constricts the flow of blood, oxygen, and nutrients to the heart muscles. With significant blockages, about 60% to 70% of the vessel wall and exertion the increased demand of blood by the heart is not met. More than 100 number of risk factors responsible for the development of CHD are documented. Williams in 1981 identified 246 risk factors that directly or indirectly lead to the development and onset of heart disease. The excess risk is closely related to the plasma concentration of LDL cholesterol and is inversely related to the plasma concentration of LDL cholesterol and is inversely related to the plasma HDL Cholesterol concentration. There is also a weak correlation between plasma triglyceride concentration and the incidence of coronary artery disease. Moreover, numerous clinical trials have shown that lowering high cholesterol concentrations by diet or drugs can reduce the risk of cardiac events. Moreover, many allopathic antihypertensive drugs have been shown to reduce coronary mortality but by less than might have been anticipated, possibly because

many of these agents have potentially adverse effects on lipid and glucose metabolism. Ayurvediya care from both the preventive and therapeutic ways like primary protection in terms of Swasthya Vritta with Aushadha along with Pathyapathya and Ashwagandha+Guggulu provide tremendous results with secondary cardio protection by their anti hyperlipidamic, antiatherosclerotic, antihypertensive actions. All the patients already on prescribed allopathic medicine and cardiac diet were taken. An attempt to evaluate the efficacy of ayurvediya Ashwagandha (***Withania somnifera***)+Shuddha guggulu in 500mg twice daily in 20 patients of atheromatous coronary hypertensive heart patients associated with obesity is made at Clinical Research Unit, Safadarjang Hospital New Delhi during 2007.

169. Miglani, A. and R. K. Manchanda (2014). "**Prospective, non-randomised, open-label study of homeopathic *Zingiber officinale* (ginger) in the treatment of acne vulgaris.**" Focus on Alternative and Complementary Therapies **19**(4): 191-197.

Zingiber officinale (ginger) has a long history of use in traditional medicine, including homeopathy. Studies carried out so far have validated some of the ethno-medicinal observations. Objective was to determine the effectiveness of homeopathic *Z. officinale* for the treatment of acne vulgaris and to identify its prescribing indications. A prospective, non-randomised open-label study was conducted on human participants with acne vulgaris. Homeopathic *Z. officinale* was prescribed in different potencies (6C up to 1M) over a period of 6 months. Outcomes included changes in lesion counts, Global Acne Grading System (GAGS) score, and Acne-Specific Quality of Life (Acne-QoL) score. Data were analysed using paired t-tests, Wilcoxon signed-rank tests and Pearson's correlation tests. Results Thirty-two participants enrolled in the study; data for 31 participants were analysed. Statistically significant ($P<0.001$) changes in lesion counts, GAGS scores and Acne-QoL scores were observed. Conclusion Homeopathic Z. officinale demonstrates encouraging results in the treatment of facial acne. Further investigation, using a randomised placebo-controlled trial design and a larger sample size is now required to draw firmer conclusions about the effectiveness of this intervention.

170. Mishra, S., N. Verma, S. Bhattacharya, K. Usman, D. Himanshu, P. Singh, B. Anjum and N. Verma (2015). "**Effect of *Tinospora cordifolia* as an add-on therapy on the blood glucose levels of patients with Type 2 diabetes.**" International Journal of Basic & Clinical Pharmacology **4**(3): 537-541.

Type 2 diabetes is a fast growing epidemic affecting people globally. Good glycemic control helps in reducing the risk of macro and microvascular complications in diabetics. Alternative medicines have been used since ancient times in India to achieve good glycemic control. ***Tinospora cordifolia*** (Tc) is a well reported plant possessing anti-diabetic property. Therefore, authors undertook this study to evaluate the effectivity of Tc in reducing the blood glucose levels of Type 2 diabetic patients in the form of add-on therapy. In the present study, authors enrolled 100 Type 2 diabetic patients who met inclusion criteria. These patients were then randomly divided into two Groups, A and B. Patients in Group A were treated as controls and they continued with their anti-diabetic medications. In Group B, Tc was added to the conventional treatment at a dose of 500 mg 3 times daily along with

meals. The fasting and postprandial blood glucose levels and glycosylated hemoglobin (HbA1c) were recorded baseline and after 6 months. During the course of study, authors observed a decrease in the fasting, postprandial, and HbA1c levels of the patients. However, this decrease was found to be more statistically significant ($p \leq 0.005$) in Group B. The results obtained from the present study conclude that Tc, when given in the form of add-on therapy, was found to be synergistic and effective in the better management of Type 2 diabetes. The drug was well tolerated by the patients and no adverse drug event was recorded.

171. Mishra, S., N. Verma, e. Bhattacharya, K. Usman, H. Reddy, N. Verma, B. Anjum, P. Singh, S. Bharadwaj and K. Bharadwaj (2015). "**Efficacy and safety of *Tinospora cordifolia* (Tc) as an add-on therapy in patients with type-2 diabetes.**" International Journal of Research in Medical Sciences **3**(5): 1109-1113.

Type 2 diabetes has become a global epidemic. ***Tinospora cordifolia*** is being used in the treatment of type 2 diabetes since ancient times. It is a common misconception that Ayurvedic medicines are always safe. In fact, they also pose serious health risks either in the form of adverse reactions or in the form of drug interactions. Hence this study was undertaken to study the efficacy and safety of Tc on human subjects. Authors recruited 40 type 2 diabetic patients who were on oral hypoglycaemic agents. These patients were then randomly divided into two groups, A and B. Patients in group A continued with their anti-diabetic medications while in group B Tc was given at a dose of 500 mg three times daily along with their conventional medications. The fasting and post prandial blood glucose levels, renal function tests and liver function tests were recorded at baseline, 3 months and 6 months. During the course of study there was observed decrease in the fasting and post prandial blood glucose levels of the patients. No significant change was observed in the renal function tests and liver function tests and no other event of any adverse drug reactions were recorded. In conclusion, ***Tinospora cordifolia*** (Tc) is effective as an add-on therapy in patients with type-2 diabetes. There is no negative impact of Tc on the renal as well as liver function tests.

172. Mittal, A. and R. Dabur (2014). "**Detection of new human metabolic urinary markers in chronic alcoholism and their reversal by aqueous extract of *Tinospora cordifolia* stem.**" Alcohol and Alcoholism **50**(3): 271-281.

Authors studied urine metabolic signature of chronic alcoholism (CA) before and after treatment with an Ayurvedic drug ***Tinospora cordifolia*** aqueous extract (TCE). Urinary metabolites of chronic alcoholics and apparently healthy subjects were profiled using HPLC-Q-TOF-MS. Discrimination models from the initial data sets were able to correctly assign the unknown samples to the CA, treated or healthy groups in validation sets with r2 > 0.98. Metabolic signature in CA patients include changed tryptophan, fatty acids and pyrimidines metabolism. Several novel biomarkers of alcoholism were observed in urine for the first time which includes, 5-hydroxyindole, phenylacetic acid, picolinic acid, quinaldic acid, histidine, cystathionine, riboflavin, tetrahydrobiopterin and chenodeoxyglycocholic acid, in addition to previously reported biomarkers. Treatment of CA with TCE reverted the levels of most of the biomarkers except tetrahydrobiopterin levels.Conclusions: These results suggested that the measurement of these urine metabolites could be used as a non-invasive

diagnostic method for the detection of CA. As TCE treatment significantly reversed the affected pathways without any side effect. Overall, the present data depicts that TCE may be used either alone or adjunct in reducing alcohol-induced disorders.

173. Mohammad, K. and B. Larijani (2013). "**A systematic review of the antioxidant, anti-diabetic, and anti-obesity effects and safety of *Triphala* herbal formulation.**" Journal of Medicinal Plants Research **7**(14): 831-844.

Triphala (TPL) is one of the oldest used polyherbal preparations. It is comprised of ***Terminalia chebula***, ***Terminalia bellirica*** and ***Emblica officinalis***. A variety of uses, such as anti-obesity, of TPL have been described in Ayurvedic and Al-Qanoon Felteb literature. This study focuses on the efficacy and safety of *Triphala* in medicines, with any outcome in humans and animals; and described some of the mechanisms responsible for the many effects of this traditional medicine and main phytochemical analysis. The databases searched include Google Scholar, PubMed, Web of Science, the search terms were "TPL" and "trifala" without narrowing or limiting search elements. The benefits of TPL in vivo and in vitro include: antioxidant, anti-hypercholesterolemic, anti-diabetic, anti-obesity, chemo-preventive potential and anti-mutagenic activity, anti-inflammatory, antimicrobial, radioprotective effect, immunomodulatory, improving wound healing, enteroprotective efficacies, anti gastric ulcers and nitric oxide scavenging activity. This herbal combination can have profound healing benefits in multi-organ systems. And, it exhibits a number of health benefits like antioxidant activity, lowers cholesterol. It is rich in Mg, K, Ca, Fe, Se and Zn, which enhance their bioavailability. TPL may be potent therapeutic agents for scavenging of NO and thereby help to explain, rejuvenating, adaptogenic, cardioprotective and neuroprotective activities of these traditional, and clinically used non toxic drugs.

174. Mukherjee, P. K., S. Rai, S. Bhattacharyya, P. K. Debnath, T. K. Biswas, U. Jana, S. Pandit, B. P. Saha and P. K. Paul (2006). "**Clinical study of '*Triphala*' - A well known phytomedicine from India.**" Iranian Journal of Pharmacology and Therapeutics **5**(1): 51-54.

Triphala' is an age old commonly used Ayurvedic powdered preparation in Indian systems of medicine. This well known formulation is made by combining ***Terminalia chebula***, ***Terminalia bellirica*** and ***Emblica officinalis***, in equal proportions based on the observation of Ayurvedic Formulary of India (AFI). The formulation is prescribed in the first line treatment of many aliments and is used as laxative, detoxifying agent and rejuvenator. To establish its clinical validity the present work was undertaken to evaluate its therapeutic potentials and adverse effects. The *Triphala* formulation was standardized by HPTLC (High Performance Thin Layer Chromatography), using Gallic acid as a marker and was subjected to clinical studies. After proper screening 160 patients of age between 16-52 years were selected for 45 days clinical study. The effectiveness of trial drugs were judged on the basis of the subjective and objective parameters. It was observed that the amount, frequency and consistency of stool were improved in *Triphala* treated group. The changes of odor, mucous, flatulence, belching and abdominal pain where also taken into account. The well being was assessed on the basis of the parameters like concentration, appetite, thirst, sleep, hyperacidity in arbitrary scoring system. *Triphala* was found to have good laxative property, help in management of hyperacidity and also improve

appetite. No adverse effect was observed in the treated group when compared to normal patients. *Triphala* can be used effectively in the treatment of constipation and other gastric problems.

175. Munshi, R., S. Bhalerao, P. Rathi, V. V. Kuber, S. U. Nipanikar and K. P. Kadbhane (2011). "**An open-label, prospective clinical study to evaluate the efficacy and safety of TLPL/AY/01/2008 in the management of functional constipation.**" Journal of Ayurveda and Integrative Medicine **2**(3): 144-152.

Functional constipation is one of the most common gastrointestinal symptoms across the globe. Its high prevalence rate, economic burden, and adverse implications on the quality of life make constipation a major public health issue. Though various treatment options are available for the management of constipation, evidence for their efficacy and safety are limited. An open-label, prospective, interventional, and exploratory clinical trial was carried out to evaluate the efficacy and safety of "TLPL/AY/01/2008" in 34 patients suffering from functional constipation. "TLPL/AY/01/2008" is an Ayurvedic proprietary polyherbal formulation in powder form, containing Isabgol husk, Senna extract, and ***Triphala*** extract. This well known formulation is made by combining ***Terminalia chebula***, ***Terminalia bellirica*** and ***Emblica officinalis***. Administration of "TLPL/AY/01/2008" for 14 days showed a significant increase in mean weekly bowel movements from 10.19 ± 05.64 to 18.29 ± 05.72 ($P<0.05$). The mean average time spent on toilet for bowel evacuation reduced significantly from 11.02 ± 05.43 minutes (baseline value) to 08.70 ± 04.72 minutes on day 14 ($P<0.05$). Mean stool form score assessed on Bristol stool form scale was improved from 02.97 ± 00.48 (baseline value) to 04.61 ± 00.84 ($P<0.05$) on day 14. A significant improvement ($P<0.05$) was also noted in straining during defecation, sensation of incomplete evacuation, sensation of anorectal blockage, and other associated symptoms of functional constipation. The significant improvement in most of the above symptoms was endured for a post-treatment observatory period of one week. All the study patients showed an excellent tolerability to the study drug. These findings suggest that "TLPL/AY/01/2008" is an effective, safe, and non-habit-forming herbal laxative formulation for the management of constipation. Comparative clinical studies with larger sample size would be able to confirm the above findings.

176. Mustafa, T. and K. C. Srivastava (1990). "**Ginger (*Zingiber officinale*) in migraine headache.**" Journal of Ethnopharmacology **29**(3): 267-273.

Migraine is considered as a neurological disorder with little convincing evidence of the involvement of some vascular phenomenon. Recent understanding of the mechanisms behind migraine pain generation and perception have considerably helped the development of modern migraine drugs. Most migraine drugs in use, i.e., ergotamine and dihydroergotamine, iprazochrome, pizotifen and diazepam; and non-steroidal antiinflammatory drugs (i.e. aspirin, paracetamol, persantin, etc.) have side-effects and are prescribed with caution for a limited duration. Ginger (***Zingiber officinale***) is reported in Ayurvedic and Tibb systems of medicine to be useful in neurological disorders. This case study brings out that at the onset of the aura 500-600 mg of powdered ginger mixed with plain water was consumed and the abortive effect of migraine headache was percievable within 30 min. Following the first dose, the above quantity of powdered ginger was consumed twice at every 4-h period on

the first day of the onset of the attack and then the above regimen was followed for another 3- 4 days. In total, 1.5- 2 g powdered ginger was consumed per day. It is proposed that administration of ginger may exert abortive and prophylactic effects in migraine headache without any side-effects.

177. Nadkarni, M. A., S. Vyas, M. Baghel and B. Ravishankar (2010). "**Randomized placebo-controlled trial of Mustadi Ghanavati in hyperlipidemia.**" AYU **31**(3): 287.

Hyperlipidemia is one of the major lifestyle disorders. Its role has been appreciated in the manifestation of serious diseases like ischemic heart disease, diabetes, stroke etc. These lifestyle diseases are a result of lifestyle factors such as overnutrition etc., which have been referred to as the Santarpanjanya Vyadhis in the classical texts. Mustadi Ghanavti is a modified form of the classical formulation Mustadi Kwath that has been advocated by Acharya Charaka for the management of Santarpanjanya Vikaras. This placebo-controlled randomized trial of Mustadi Ghanavati (containing many herbs including ***Triphala***) was carried out on 61 patients suffering from hyperlipidemia; of the 61 patients, 50 completed the entire course of treatment. The results of the study revealed that Mustadi Ghanavati decreased serum cholesterol by 22.4%, serum triglycerides by 19.6%, serum LDL by 18.2%, and serum VLDL by 4.2%; serum HDL increased by 5.6%. Thus Mustadi Ghanavati was able to effect a total improvement of 58.8% in the lipid profile. It brought about mild improvement in 42.86% of patients and moderate improvement in 14.28% of patients. Mustadi Ghanavati was also found to have a significant effect on other subjective as well as objective parameters considered for the study. hese drugs relieve the body of excess of Kapha, Meda, Kleda, Vasa, and Sweda by diminishing their Drava Guna. Drugs like Neem, Patha, and *Triphala* bring about augmentation of the digestive fire, leading to proper formation of the Rasadi Dhatus. Patha, Musta, *Triphala*, Haridra, and Daruharidra digest the Ama Dosha present at the Jatharagni level as well as the Medodhatvagni level. Also drugs like *Triphala* (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) and Khadir are Rasayana in nature, leading to the formation of optimal Dhatus, and thereby protect the body from injury due to vitiated Doshas.

178. Nagashayana, N., P. Sankarankutty, M. R. V. Nampoothiri, P. K. Mohan and K. P. Mohanakumar (2000). "**Association of L-DOPA with recovery following Ayurveda medication in Parkinson's disease.**" Journal of the Neurological Sciences **176**(2): 124-127.

Ayurveda, the Indian system of traditional medicine, uses a concoction of several spices, herbs and minerals for the treatment of diseases. In a clinical prospective study authors evaluated the efficacy of Ayurveda treatment (a concoction in cow's milk of powdered *Mucuna pruriens* and *Hyoscyamus reticulatus* seeds and ***Withania somnifera*** and *Sida cordifolia* roots) in 18 clinically diagnosed (with a mean Hoen and Yahr value of 2.22) parkinsonian patients. As per Ayurveda principles, 13 patients underwent both cleansing (for 28 days) and palliative therapy (56 days), 5 patients underwent palliative therapy alone (84 days). Only the former group showed significant improvement in activities of daily living (ADL) and on motor examination as per UPDRS rating. Symptomatically, they exhibited better response in tremor, bradykinesia, stiffness and cramps as compared to the latter group. Excessive salivation worsened in both the groups. Analyses of powdered samples in milk, as administered in patients, revealed about 200 mg of L-DOPA per dose. The study

establishes the necessity of cleansing therapy in Ayurveda medication prior to palliative therapy. It also reveals contribution of L-DOPA in the recovery as observed in Parkinson' disease following Ayurveda medication.

179. Naiktari, R. S., P. Gaonkar, A. N. Gurav and S. V. Khiste (2014). "**A randomized clinical trial to evaluate and compare the efficacy of *Triphala* mouthwash with 0.2% chlorhexidine in hospitalized patients with periodontal diseases.**" Journal of Periodontal and Implant Science **44**(3): 134-140.

Triphala is a combination of three medicinal plants, extensively used in Ayurveda since ancient times (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***). *Triphala* mouthwash is used in the treatment of periodontal diseases because of its antimicrobial and antioxidant properties. The aim of this study is to compare the efficacy of *Triphala* mouthwash with 0.2% chlorhexidine in hospitalized periodontal disease patients. In this double-blind, randomized, multicenter clinical trial, 120 patients were equally divided into three groups. Patients in group A were advised to rinse their mouths with 10 mL of distilled water, group B with 0.2% chlorhexidine, and group C with *Triphala* mouthwash for 1 minute twice daily for two weeks. The plaque index (PI) and the gingival index (GI) were recorded on the first and the fifteenth day. Results: There was no significant difference when the efficacy of *Triphala* was compared with 0.2% chlorhexidine in hospitalized patients with periodontal disease. However, a statistically significant difference was observed in PI and GI when both group B and group C were compared with group A and also within groups B and C, after 15 days ($P<0.05$). The *Triphala* mouthwash (herbal) is an effective antiplaque agent like 0.2% chlorhexidine. It is significantly useful in reducing plaque accumulation and gingival inflammation, thereby controlling periodontal diseases in every patient. It is also cost effective, easily available, and well tolerable with no reported side effects.

180. Nandhini, T. and R. V. Geetha (2015). "**Comparison of the effectiveness of a commercially available herbal mouth rinse with chlorhexidine gluconate at the clinical and patient level.**" Journal of Pharmaceutical Sciences and Research **7**(8): 595-597.

Oral hygiene is the practice of keeping the mouth clean and healthy by brushing and flossing to prevent tooth decay and gum disease. The purpose of oral hygiene is to prevent the build up of plaque, the sticky film of bacteria and food that forms on the teeth. The removal of plaque is utmost important to control dental caries. The key to good oral health is hidden in nature. Natural herbs like neem, tulsi, pudina, clove oil, ajwain, ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) and many more has been used since ages either as a whole single herb or as a combination against various oral health problems like bleeding gums, halitosis, mouth ulcers and preventing tooth decay. So the aim of the present study is to compare the effectiveness of a herbal mouth rinse with chlorhexidine gluconate mouth rinse at the clinical level in reducing Streptococcus mutans count. A randomized study was carried out on 30 patients who have dental caries. Out of which 15 subjects were given herbal mouthwash to rinse twice a day for five days. The other 15 were given 0.12% chlorhexidine mouthwash to rinse twice a day for five days. Saliva sample were collected prior to the use of mouth wash and after five days and Sreptococcus mutans count was done in terms of colony forming units per ml

(CFU/ml). The results of the present study showed that herbal mouthwash can cause inhibition of bacterial growth.

181. Narayan, A. and C. Mendon (2012). "**Comparing the effect of different mouthrinses on de Novo plaque formation.**" Journal of Contemporary Dental Practice **13**(4): 460-463.

Several antiplaque agents are being available in the market in spite of vast development of modern medical science, satisfactory treatment of 'oral diseases' by newer drugs is not fully achieved, rather the chemical compounds has exposed the patients to it is different ill effects, therefore, there is interest to find out effective remedy of any disease by harmless herbal drugs thus the aim of this study was to compare plaque formation at 24 hours after the use of ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***), Hi ora, Chlorhexidine and colgate plax mouth washes. Methods: A controlled, randomized, double-blind, crossover clinical trial was designed. Thirty subjects underwent four consecutive experimental phases with four treatments: *Triphala*, Hi Ora, Chlorhexidine and colgate plax. On the day of study, the subjects discontinued all other oral hygiene habits and were randomly assigned for treatment with the experimental mouthwash. Each experimental phase was preceded by a 28- day washout period. Plaque formation was recorded after one undisturbed day. *Triphala*, Hi Ora and Chlorhexidine reduced de novo plaque formation to a greater extent than the colgate plax mouthwash ($p < 0.05$). *Triphala* and Hi Ora (with *Triphala* (*Emblica officinalis*, *Terminalia bellirica*, *Terminalia chebula*) and ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) among other ingredients) presents an anti-plaque efficacy similar to that of chlorhexdine, and was more effective at inhibiting plaque formation than the colgate plax mouth wash.

182. Nayak, S. S., A. V. Ankola, S. C. Metgud and U. Bolmal (2012). "**Effectiveness of mouthrinse formulated from ethanol extract of *Terminalia chebula* fruit on salivary Streptococcus mutans among 12 to 15 year old school children of Belgaum city: A randomized field trial.**" Journal of Indian Society of Pedodontics and Preventive Dentistry **30**(3): 231-236.

Dental caries is the most prevalent oral disease. Streptococcus mutans plays a major role in the occurrence of dental caries. Many antibacterial agents have been developed against dental caries. However, they lack the qualities of an ideal agent. Thus presently, antibacterial activity of herbal agents is being extensively studied. Ethanol extract of ***Terminalia chebula*** was prepared and mouthrinse was formulated. A total of 60 children meeting the inclusion criteria were randomly divided into study and control group and respective mouthrinses were administered. Salivary Streptococcus mutans count was assessed at 5 and 60 minutes after rinsing and compared with baseline values. Substantivity of the rinse was assessed among 10 children. Mouthrinse was given to the children and salivary Streptococcus mutans counts were assessed at baseline, 6 and 12 hours postrinsing. Mann-Whitney U test was used to assess the variance of factors like Decayed Missed Filled Teeth, plaque scores, and gingival scores. ANCOVA (Analysis of covariance) was used to determine the change in salivary Streptococcus mutans colony forming units taking baseline values as covariates. It was observed that there was 44.42% reduction in salivary Streptococcus mutans colony forming units 5 minutes after rinsing as compared with baseline values and 64.14% reduction in Streptococcus mutans colony forming units

at 60 minutes after rinsing as compared with baseline values. There was a reduction of 35.48% in salivary Streptococcus mutans colony forming units at 60 minutes after rinsing as compared with 5 minutes sample. Streptococcus mutans counts were low up to 6 hours postrinsing among 80% of the children.

183. Nieman, D. C., R. A. Shanely, B. Luo, D. Dew, M. P. Meaney and W. Sha (2013). "**A commercialized dietary supplement alleviates joint pain in community adults: A double-blind, placebo-controlled community trial.**" Nutrition Journal **12**(1).

The purpose of this study was to assess the effect of 8-weeks ingestion of a commercialized joint pain dietary supplement (InstaflexTM Joint Support, Direct Digital, Charlotte, NC) compared to placebo on joint pain, stiffness, and function in adults with self-reported joint pain. InstaflexTM is a joint pain supplement containing glucosamine sulfate, methylsufonlylmethane (MSM), white willow bark extract (15% salicin), ginger (***Zingiber officinale***) root concentrate, *Boswella serrata* extract (65% boswellic acid), turmeric root extract, cayenne, and hyaluronic acid. Subjects included 100 men and women, ages 50-75 years, with a history (>3 months) of joint pain, and were randomized to Instaflex™ or placebo (3 colored gel capsules per day for 8 weeks, double-blind administration). Subjects agreed to avoid the use of non-steroidal anti-inflammatory drugs (NSAID) and all other medications and supplements targeted for joint pain. Primary outcome measures were obtained pre- and post-study and included joint pain severity, stiffness, and function (Western Ontario and McMaster Universities [WOMAC]), and secondary outcome measures included health-related quality of life (Short Form 36 or SF-36), systemic inflammation (serum C-reactive protein and 9 plasma cytokines), and physical function (6-minute walk test). Joint pain symptom severity was assessed bi-weekly using a 12-point Likert visual scale (12-VS). Results: Joint pain severity was significantly reduced in Instaflex™ compared to placebo (8-week WOMAC, ↓37% versus ↓16%, respectively, interaction effect P = 0.025), with group differences using the 12-VS emerging by week 4 of the study (interaction effect, P = 0.0125). Improvements in ability to perform daily activities and stiffness scores in Instaflex™ compared to placebo were most evident for the 74% of subjects reporting knee pain (8-week WOMAC function score, ↓39% versus ↓14%, respectively, interaction effect P = 0.027; stiffness score, ↓30% versus ↓12%, respectively, interaction effect P = 0.081). Patterns of change in SF-36, systemic inflammation biomarkers, and the 6-minute walk test did not differ significantly between groups during the 8-week study. Results from this randomized, double blind, placebo-controlled community trial support the use of the Instaflex™ dietary supplement in alleviating joint pain severity in middle-aged and older adults, with mitigation of difficulty performing daily activities most apparent in subjects with knee pain. Trial registration. ClinicalTrials.gov Identifier: NCT01956500.

184. Niempoog, S., P. Siriarchavatana and T. Kajsongkram (2012). "**The efficacy of Plygersic gel for use in the treatment of osteoarthritis of the knee.**" Journal of the Medical Association of Thailand **95 Suppl 10**: S113-119.

An evaluation of the efficacy of the combination of ginger (***Zingiber officinale***) and plai (*Zingiber cassumunar*) gel for the treatment of osteoarthritis of the knee using 1% diclofenac gel as a comparator. A double-blind, randomized, controlled trial of

the combination of 4% ginger and plai extract in a gel (Plygersic gel) as compared with a 1% solution of diclofenac in patients with osteoarthritis knees. The number of participants in each group totaled fifty. The length of treatment was a 6 week period. The efficacy of the drugs was monitored by using the Knee Injury and Osteoarthritis Outcome Score (KOOS). The t-test was used to compare the scores before and after treatments in each group. The repeated ANOVA was used to compare the scores between the two groups. Both Plygersic gel and diclofenac gel could significantly improve knee joint pain, symptoms, daily activities, sports activities and quality of life measured by KOOS following 6 weeks of treatment. In the repeated ANOVA, there were no differences in the results between the Plygersic and diclofenac gel groups. Plygersic gel relieves joint pain and improves problematic symptoms and improves the quality of life in osteoarthritis knees during a 6 week treatment regimen with no differences to the 1% Diclofenac gel group.

185. Nipanikar, S. U., M. Saluja, V. V. Kuber, K. P. Kadbhane, A. Chopra and N. R. Khade (2013). "**An open label, prospective, clinical study on a polyherbal formulation in osteoarthritis of knee.**" Journal of Ayurveda and Integrative Medicine **4**(1): 33-39.

Currently, though pharmacological, mechanical, and surgical interventions are used, there is no known cure for osteoarthritis (OA). The main aim of the study was to assess the efficacy and safety of «TLPL/AY/03/2008, a polyherbal formulation on knee joint pain assessed on visual analogue scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). It was an open label, single center, prospective, clinical study conducted in 36 patients of OA Knee. Two capsules of 'TLPL/AY/03/2008' were given to all patients twice daily orally after meals for 180 days. Data describing quantitative measures are expressed as mean ± SD. Comparison of variables representing categorical data was performed using Chi-square test. The mean joint pain (as assessed on VAS) reduced significantly (59.85%; $P < 0.05$) and the mean WOMAC combined score, WOMAC pain sub-score, WOMAC stiffness sub-score, and WOMAC difficulty sub-score also reduced significantly at the end of the study. The mean time taken by the patients to walk 50 feet too, was reduced significantly (25.26%) at the end of the study. At the end of 4 months of the treatment, no patient needed paracetamol as rescue medicine to control pain. Most of the patients had shown good overall improvement assessed by the physician and by the patients. Majority of the patients showed excellent tolerability to the study drug. No significant change in most of the safety laboratory parameters was observed at the end of the study. The study provides good evidence in support of the efficacy and safety of the 'TLPL/AY/03/2008' in OA of knee. Thr drugs involved in the research include *Boswellia serrata* extract; *Commiphora mukul* extract; ginger (***Zingiber officinale***) extract; *Nyctanthes arbortristis* extract; *Vitex negundo* extract; ***Withania somnifera*** extract among others.

186. Nostro, A., L. Cellini, S. Di Bartolomeo, M. A. Cannatelli, E. Di Campli, F. Procopio, R. Grande, L. Marzio and V. Alonzo (2006). "**Effects of combining extracts (from propolis or *Zingiber officinale*) with clarithromycin on Helicobacter pylori**." Phytotherapy Research **20**(3): 187-190.

Propolis and ***Zingiber officinale*** have been shown to be specifically targeted against Helicobacter pylori strains, to possess antiinflammatory, antioxidant and antitumoral

activity and to be used in traditional medicine for the treatment of gastrointestinal ailments. Considering that these natural products could potentially serve as novel therapeutic tools also in combination with an antibiotic, the aim of this work was to evaluate their effect when combined with clarithromycin on clinical H. pylori isolates (n = 25), characterized in respect to both clarithromycin susceptibility and the presence of the cagA gene. The results showed that the combinations of propolis extract + clarithromycin and Z. officinale extract + clarithromycin exhibited improved inhibition of H. pylori with synergistic or additive activity. Interestingly, the susceptibility to combinations was significantly independent of the microbial clarithromycin susceptibility status. Only one H. pylori strain showed antagonism towards the *Z. officinale* extract + clarithromycin combination. The data demonstrate that combinations of propolis extract + clarithromycin and Z. officinale extract + clarithromycin have the potential to help control H. pylori-associated gastroduodenal disease.

187. Pal, S. K. and S. H. Fatima (2014). "**Cancer treatment with the alternative herbal medicine HUMA: Two case reports.**" Middle East Journal of Cancer **5**(1): 41-46.

Complementary and alternative medicine is popular among cancer patients worldwide. Among these, herbal medicines have a substantial place in cancer treatment and palliation. Cancer patients in the Western world use complementary and alternative medicine in conjunction with conventional care. However, the situation in a developing country such as India that has some highest cancer rates worldwide is alarming. Lack of early screening and treatment facilities coupled with high cost of treatment often compels patients to seek alternative measures for treatment. Authors discuss two cancer patients with advanced disease who tried an alternative poly herbal therapy (HUMA). This herbal formulation was derived from various important Ayurvedic herbs viz. *Azadirachta indica*, *Curcuma longa*, ***Emblica officinalis***, *Ocimum sanctum*, *Semecarpus anacardium*, and ***Tinospora cordifolia***, among others. A male patient 59 years of age with disseminated malignant disease of either pseudomyxoma peritonei or metastatic mucinous adenocarcinoma showed immense benefit by this therapy with complete regression of his malignancy. The patient completed five years of disease-free survival after cessation of therapy. The second case, a 33-year old male patient diagnosed with rectal carcinoma and multiple metastatic lesions in his liver underwent HUMA therapy with stabilization in his disease progression for an 11-month period. In this case, treatment with HUMA was helpful in palliative care. No adverse effects were noted in either patient.

188. Pal, S. K. and S. H. Fatima (2014). "**Cancer treatment with the alternative herbal medicine HUMA: Two case reports.**" Middle East Journal of Cancer **5**(1): 41-46.

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189. Palatty, P. L., R. Haniadka, B. Valder, R. Arora and M. S. Baliga (2013). "**Ginger in the Prevention of Nausea and Vomiting: A Review.**" Critical reviews in food science and nutrition **53**(7): 659-669.

Nausea and vomiting are physiological processes experienced by every human being at some stage of their life. They are complex protective mechanisms and the symptoms are influenced by the emetogenic response and stimuli. However, when these symptoms recur frequently, they can significantly reduce the quality of life and can also be detrimental to health. The existing antiemetic agents are ineffective against certain stimuli, are expensive, and possess side effects. Herbal medicines have been shown to be effective antiemetics, and among the various plants studied, the rhizome of ***Zingiber officinale***, commonly known as ginger, has been used as a broad-spectrum antiemetic in the various traditional systems of medicine for over 2000 years. Various preclinical and clinical studies have shown ginger to possess antiemetic effects against different emetogenic stimuli. However, conflicting reports especially in the prevention of chemotherapy-induced nausea and vomiting and motion sickness prevent from drawing any firm conclusion**.** The current review for the first time summarizes the results. An attempt is also made to address the lacunae in these published studies and emphasize aspects that need further investigations for it to be of use in clinics in the future.

190. Paramdeep, G. (2013). "**Efficacy and tolerability of ginger (*Zingiber officinale*) in patients of osteoarthritis of knee.**" Indian Journal of Physiology and Pharmacology **57**(2): 177-183.

Osteoarthritis (OA) is a chronic degenerative disorder of synovial joints and a common cause of locomotor disability. NSAIDs are routinely used for symptomatic treatment and are associated with side effects which have led to the increased interest towards alternative treatment options. This study was conducted to evaluate the safety and efficacy of ginger (***Zingiber officinale***) in management of OA. Sixty patients of OA of knee were enrolled in randomized open label study and divided into three groups of 20 each. Group I received tab. Diclofenac 50 mg and cap. placebo, group II received cap. ginger 750 mg and cap. placebo and group III received cap. ginger 750 mg and tab. diclofenac 50 mg. The assessment of efficacy was done at every 2 weeks till 12 weeks, by using Western Ontario and McMaster Universities osteoarthritis (WOMAC) index, Visual Analogue Scale (VAS) and the safety assessment was done by noting adverse events during the study. The analysis

of WOMAC score and VAS score in all the three groups showed statistically significant improvement with time in all groups. On comparison among three groups, group III patients who received both ginger and diclofenac showed numerically superior improvement than the individual treatments. There was no statistically significant difference among three groups in case of adverse events. Ginger powder has add-on effect on reducing the symptoms of OA of knee with acceptable safety profile.

191. Paranjpe, P., P. Patki and B. Patwardhan (1990). "**Ayurvedic treatment of obesity: A randomised double-blind, placebo-controlled clinical trial.**" Journal of Ethnopharmacology **29**(1): 1-11.

Seventy obese subjects were randomised into four groups. Ayurvedic drug including ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) and ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) among many other herbs were given for three months while one group received a placebo. Physical, clinical and pathological investigations were carried out at regular intervals. A significant weight loss was observed in drug therapy groups when compared with the placebo. Body measurements such as skin fold thickness and hip and waist circumferences were significantly decreased. Decreases in serum cholesterol and triglyceride levels were observed. No side effects of any kind were observed during the treatment period.

192. Paranjpe, P. and P. H. Kulkarni (1995). "**Comparative efficacy of four Ayurvedic formulations in the treatment of acne vulgaris: A double-blind randomised placebo-controlled clinical evaluation.**" Journal of Ethnopharmacology **49**(3): 127-132.

Eighty-two patients with acne vulgaris were randomised into five groups. Four different Ayurvedic treatment schedules were given orally for 6 weeks, while one group received a placebo. Physical and clinical investigations were carried out at 2 week intervals. The drug also contains ***Triphala*** species (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***). A significant reduction in lesion count was observed in patients receiving Sunder Vati when compared with the placebo and the other Ayurvedic formulations, which failed to produce any significant difference from the pretreatment condition. The drug therapies were well tolerated.

193. Paranjpe, P., P. Patki and N. Joshi (2000). "**Efficacy of an indigenous formulation in patients with bleeding piles: A preliminary clinical study.**" Fitoterapia **71**(1): 41-45.

Piles (haemorrhoids) result in rectal bleeding. The results of the clinical assessment of a multiherbal indigenous formulation (*Berberis aristata*, *Holarrhena antidysenterica*, *Picrorrhiza kurroa*, *Mesua ferrea*, ***Terminalia chebula***, ***Terminalia bellirica***, ***Emblica officinalis***) on 22 patients with bleeding piles has been found very useful. The present study indicates that indigenous therapy was beneficial to patients with bleeding piles. The tried multiherbal formulation also reduced constipation, discharge and rectal bleeding.

194. Patil, S., B. Santosh, S. Maheshwari, A. Deoghare, S. Chhugani and P. Rajesh (2015). "**Efficacy of oxitard capsules in the treatment of oral submucous fibrosis.**" Journal of Cancer Research and Therapeutics **11**(2): 291-294.

Oral submucous fibrosis (OSMF) is a high-risk premalignant condition predominantly seen in the Indian subcontinent. The aim of the present study was to evaluate the efficacy of oxitard capsules in the management of OSMF. The formulation of the oxitard capsules contains the extracts of *Mangifera indica*, ***Withania somnifera***, *Daucus carota*, *Glycyrrhiza glabra*, *Vitis vinifera*, powders of ***Emblica officinalis*** and Yashada bhasma, and oils of *Triticum sativum*. Total of 120 subjects with clinico-pathologically diagnosed OSMF were included in the study and divided equally in 2 groups; Group A (oxitard group) and Group B (placebo group). Group A was administered 2 oxitard capsules twice daily and Group B was given placebo tablets twice daily, for 3 months. Evaluation for different clinical parameters was done at regular intervals and data was analyzed using the Student's paired t test and Chi-square test. $P < 0.001$ was considered to be statistically significant. Clinical improvements in mouth-opening and tongue protrusion were significant in the Group A ($P < 0.001$). Subjective symptoms of burning sensation ($P = 0.0001$), pain associated with the lesion ($P = 0.000$), difficulty in swallowing ($P = 0.0003$) and speech ($P = 0.0005$) also significantly improved in the Group A. There was a mild to moderate decrease in the size of the lesion. Though there is no definitive treatment for the condition; however, oxitard capsules can bring about significant clinical improvements in the symptoms like mouth-opening, tongue protrusion, burning sensation, difficulty in swallowing and speech and pain associated with the lesion, thereby improving the quality of life of the affected individuals.

195. Patel, M. V., S. Gupta and N. G. Patel (2011). "**Effects of Ayurvedic treatment on 100 patients of chronic renal failure (other than diabetic nephropathy)**." AYU **32**(4): 329-332.

Chronic renal failure (CRF) refers to an irreversible deterioration in renal function, which develops over a period of years. This initially manifests only as a biochemical abnormality. CRF is considered when glomerular filtration rate (GFR) falls below 30 ml/min. The conventional approach of management includes dialysis and renal transplantation, which are not affordable by Indian population mainly due to economic reasons. Therefore, exploration of a safe and alternative therapy is needed, which proves to be helpful in reducing the requirement of dialysis and in postponing the renal transplantation. A clinical study of 100 patients of CRF was conducted at OPD and IPD of PD Patel Ayurved Hospital, Nadiad. They were given Niruha basti of Punarnavadi kvatha daily with oral medicaments including Goksuradi guggulu, Rasayana churna, and Varunadi kvatha for 1 month period. Treatment contained Goksuradi guggulu (compound Ayurvedic preparation: Gokshura+Guggulu+***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***)+***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***)+Musta) 1 g three times a day. Rasayan churna Gokshura + Amalaki (***Emblica officinalis***) + Guduchi (***Tinospora cordifolia***) in equal quantities) 3 g two times a day. Varunadi kvath (ingredients: Varuna tvak + Bilva moola + Apamarga + Chitrak moola + Arani + Shigru + Bruhati + Kirattikta + Karanja + Shatavari) 10 g two times/day. Niruha basti of Punarnavadi kvatha daily. The patients of CRF, having diabetic nephropathy as a cause, were excluded since a separate study for diabetic nephropathy is being conducted. Results were analyzed statistically using the "t " test. The symptoms and signs, serum creatinine, blood urea, urine albumin level were reduced, which were found to be statistically highly significant on "t " test. With the help of clinical observations and the discussion made,

it may be concluded that 86% patients of CRF have hypertension as a basic underlying cause. The result obtained may be attributed to the disease modifying effect of trial therapy by means of its Rasayana and anti Vata-Kapha properties. The trial therapy is an ideal drug as a safe and effective alternative in case of CRF. Serum creatinine, blood urea and albuminuria reduced 20.71%, 32.15% and 36.70%, respectively. Hemoglobin level and urine output increased by 4.38% and 56.54%, respectively. They were statistically highly significant. All the patients have shown more than 50% relief in all the signs and symptoms. In a difficult condition where conventional treatments are beyond the financial capacities of a common man of the country, this therapy can be hopeful and promising.

196. Pathak, M., H. Vyas and M. K. Vyas (2010). "**A clinical trial of Pippali (*Piper longum* Linn.) with special reference to Abheshaja.**" AYU **31**(4): 442-446.

The classification of Dravya has been undertaken in many ways, but according to the medicinal value, they are mainly divided into two - Bheshaja and Abheshaja. No study has been documented on Abheshaja to date as per the scholar's knowledge. Therefore, the present study was carried out to understand the concept of Abheshaja by a practical study. The drug Pippali (***Piper longum*** Linn.) has been contraindicated to be used for a longer duration. A clinical study was carried out on patients with Kaphaja Kasa, to evolve and assess if the drug acts as Abheshaja or not, and if yes, then under what circumstances. The patients of Kaphaja Kasa had been selected by the random sampling method. They were randomly divided into two groups - Group A and Group B. In Group A, test drug Pippali Churna was administered. Group B was a standard control group and Vasa Churna was given to this group. The dose of both the drugs was 4 g B.I.D. The result was assessed after three weeks of drug administration with the help of a specially prepared proforma. All the important hematological, biochemical, urine, and stool investigations were carried out. There was no adverse drug reaction (ADR) observed after the administration of Pippali in this particular study.

197. Patil, Y. R. (2012). "**An open label clinical study to evaluate effect of juice of *Tinospora cordifolia* Linn. on growth of children.**" International Journal of Research in Ayurveda and Pharmacy **3**(1): 77-79.

Guduchi (***Tinospora cordifolia***) is being used as a rejuvenating herb in Ayurveda and other system of medicine since many decades. Guduchi is prescribed as a monoherbal as well as polyherbal formulation. The herb has free radical scavenging properties against reactive oxygen and nitrogen. Due to its Rasayana (free radical scavenging property) it was decided to evaluate efficacy of its juice in growth of children by comparing with standard growth charts developed by National centre for health statistics. 30 Children of age group 6 to 8 years were recruited in the trial. Children were assessed and evaluated on the basis of objective and subjective parameters at interval of 15 days for 3 months. Mean weight of children at baseline of study was 19.99 ± 1.59 kg and was increased moderately to 20.64 ± 1.57 kg (at 12th wk). Mean score of skin luster was 0.43 ± 0.5 and it was increased significantly to 1.17 ± 0.37. Diet intake of these children at baseline was 0.467 ± 0.51 and in was increased significantly to 1.63 ± 0.48. These findings suggest that juice of ***Tinospora cordifolia*** is an effective, safe, and herbal formulation for the children growth.

198. Perera, P. K., M. Perera and N. Kumarasinghe (2014). "**Effect of Sri Lankan traditional medicine and Ayurveda on Sandhigata Vata (osteoarthritis of knee joint).**" AYU **35**(4): 411-415.

Reported case was a 63-year-old female with end-stage osteoarthritis (OA) (Sandhigata Vata) of the left knee joint accompanied by exostoses. Radiology (X-ray) report confirmed it as a Kellgren-Lawrence grade III or less with exostoses. At the beginning, the Knee Society Rating System scores of pain, movement and stability were poor, and function score was fair. Srilankan traditional and Ayurveda medicine treatment was given in three regimens for 70 days. After 70 days, external treatment of oleation and 2 capsules of Shallaki (*Boswellia serrata* Triana and Planch) and two tablets of Jeewya (comprised of ***Emblica officinalis*** Gaertn., ***Tinospora cordifolia*** [Willd.] Millers. and ***Terminalia chebula*** Retz.), twice daily were continued over 5 months. Visual analogue scale for pain, knee scores in the Knee Society online rating system and a Ayurveda clinical assessment criteria was used to evaluate the effects of treatments in weekly basis. After treatment for 70 days, the Knee Society Rating System scores of pain, movement and stability were also improved up to good level and function score was improved up to excellent level. During the follow-up period, joint symptoms and signs and the knee scores were unchanged. In conclusion, this OA patient's quality of life was improved by the combined treatment of Sri Lankan traditional medicine and Ayurveda.

199. Pereira, M. M., R. Haniadka, P. P. Chacko, P. L. Palatty and M. S. Baliga (2011). "***Zingiber officinale*** **Roscoe (ginger) as an adjuvant in cancer treatment: A review.**" Journal of B.U.ON (Official Journal of the Balkan Union of Oncology) **16**(3): 414-424.

Despite acquiring a strong understanding of the molecular basis and advances in treatment, cancer is the second major cause of death in the world. In clinics, the stage-dependent treatment strategies may include surgery, radiotherapy and systemic treatments like hormonotherapy and chemotherapy, which are associated with side effects. The use of traditional herbal medicine in cancer patients is on a rise, as it is believed that these medications are non toxic and alleviate the symptoms of cancer, boost the immune system, or may tackle the cancer itself. Since antiquity the rhizome of ***Zingiber officinale*** Roscoe commonly known as ginger (family Zingiberaceae) have widely been used as a spice and condiment in different societies. Additionally, ginger also has a long history of medicinal use in various cultures for treating common colds, fever, to aid digestion, treat stomach upset, diarrhoea, nausea, rheumatic disorders, gastrointestinal complications and dizziness. Preclinical studies have also shown that ginger possesses chemopreventive and antineoplastic properties. It is also reported to be effective in ameliorating the side effects of γ-radiation and of doxorubicin and cisplatin; to inhibit the efflux of anticancer drugs by P-glycoprotein (P-gp) and to possess chemosensitizing effects in certain neoplastic cells in vitro and in vivo. The objective of this review is to address observations on the role of ginger as adjuvant to treatment modalities of cancer. Emphasis is also placed on the drawbacks and on future directions for research that will have a consequential effect on cancer treatment and cure.

200. Phetkate, P., T. Kummalue, Y. U-Pratya and S. Kietinun (2012). "**Significant increase in cytotoxic T lymphocytes and natural killer cells by *Triphala*: A clinical phase I study.**" Evidence-based Complementary and Alternative Medicine **2012**. Article ID 239856.

Searching for drugs or herbal formulations to improve the immunity of HIV/AIDS positive people is an important issue for researchers in this field. ***Triphala*** (note: ***Triphala* is claimed by the authors in this article as a Thai herbal formulation!**), is reported to have immunomodulatory effects in mice. However, it has not yet been investigated for immunostimulatory and side effects in healthy human volunteers. Objective here was to evaluate the immunostimulatory and side effects of ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) in a clinical phase I study. All volunteers took ***Triphala***, 3 capsules per day for 2 weeks. Complete physical examination, routine laboratory analysis, and immunological studies were performed before ingestion and after initial meeting for 4 consecutive weeks. It was found that ***Triphala*** demonstrated significant immunostimulatory effects on cytotoxic T cells (CD3 -CD8+) and natural killer cells (CD16+CD56 +). Both of them increased significantly when compared with those of the control samples. However, no significant change in cytokine secretion was detected. All volunteers were healthy and showed no adverse effects throughout the duration of the study. ***Triphala*** has significant immunostimulatory effects on cellular immune response, especially cytotoxic T cells and natural killer cells. Increases in the absolute number of these cells may provide a novel adjuvant therapy for HIV/AIDS positive people in terms of immunological improvement.

201. Pillai, A. K., K. K. Sharma, Y. K. Gupta and S. Bakhshi (2011). "**Anti-emetic effect of ginger powder versus placebo as an add-on therapy in children and young adults receiving high emetogenic chemotherapy.**" Pediatric Blood & Cancer **56**(2): 234-238.

Chemotherapy-induced nausea and vomiting (CINV) are major adverse effects of chemotherapy. Ginger (***Zingiber officinale***) has been used in postoperative and pregnancy-induced nausea and vomiting. Data on its utility in reducing CINV in children and young adults are lacking. Sixty chemotherapy cycles of cisplatin/doxorubicin in bone sarcoma patients were randomized to ginger root powder capsules or placebo capsules as an additional antiemetic to ondensetron and dexamethasone in a double-blind design. Acute CINV was defined as nausea and vomiting occurring within 24 hr of start of chemotherapy (days 1–4) and delayed CINV as that occurring after 24 hr of completion of chemotherapy (days 5–10). CINV was evaluated as per Edmonton's Symptom Assessment Scale and National Cancer Institute criteria respectively. Acute moderate to severe nausea was observed in 28/30 (93.3%) cycles in control group as compared to 15/27 (55.6%) cycles in experimental group ($P = 0.003$). Acute moderate to severe vomiting was significantly more in the control group compared to the experimental group [23/30 (76.7%) vs. 9/27 (33.33%) respectively ($P = 0.002$)]. Delayed moderate to severe nausea was observed in 22/30 (73.3%) cycles in the control group as compared to 7/27 (25.9%) in the experimental group ($P < 0.001$). Delayed moderate to severe vomiting was significantly more in the control group compared to the experimental group [14/30 (46.67%) vs. 4/27 (14.81%) ($P = 0.022$)]. Ginger root powder was effective in reducing severity of acute and delayed CINV as additional therapy to ondensetron and dexamethasone in patients receiving high emetogenic chemotherapy (ClinicalTrials.gov identifier: NCT00940368).

202. Pingali, U., P. V. Kishan, F. Nishat and C. U. Kumar (2014). "**A comparative study to evaluate the effect of highly standardised aqueous extracts of *Phyllanthus emblica*, *Withania somnifera* and their combination on endothelial dysfunction and biomarkers in patients with type II Diabetes Mellitus.**" International Journal of Pharmaceutical Sciences and Research (IJPSR) **5**(7): 2687-2697.

Biomarkers of oxidative stress and endothelial dysfunction play an important role in the pathogenesis of type II Diabetes Mellitus (DM). The present study was planned to compare the effect of highly standardised aqueous extract of ***Phyllanthus emblica***, ***Withania somnifera*** and their combination on endothelial dysfunction and biomarkers of oxidative stress in patients with type II DM. After taking IEC approval and written informed consent, eligible patients were randomized to receive either one of the three treatments, one capsule of ***Phyllanthus emblica*** 500 mg twice daily, one capsule of ***Withania somnifera*** 500 mg twice daily or one capsule of combination of ***Phyllanthus emblica*** 250 mg+***Withania somnifera*** 250 mg twice daily for a duration of 12 weeks. Efficacy end points were change in endothelial function, change in biomarkers of oxidative stress and systemic inflammation measured at baseline and after 12 weeks of treatment. Thirty patients completed the study. Twelve weeks treatment with ***Phyllanthus emblica***, ***Withania somnifera*** and their combination produced significant reduction in Reflection index (RI) compared to baseline, (-2.17±0.72% Vs -10.09±0.86), (-2.29±0.91% Vs -9.4±1.80%) and (-2.18±1.01% Vs -9.21±1.22%) respectively, suggesting improvement in endothelial function. There was also significant reduction in the biomarkers of oxidative stress and systemic inflammation. All three treatments were well tolerated. ***Phyllanthus emblica*** and ***Withania somnifera*** and their combination have shown significant improvement in endothelial function, reduction in biomarkers of oxidative stress and systemic inflammation in patients with type II DM. On further analysis, ***Phyllanthus emblica*** has shown a better response compared to other treatment groups.

203. Pingali, U., P. Raveendranadh and F. Nishat (2014). "**Effect of standardized aqueous extract of *Withania somnifera* on tests of cognitive and psychomotor performance in healthy human participants.**" Pharmacognosy Research **6**(1): 12-18.

Withania somnifera is an herbal medicine that has been known to possess memory-enhancing properties. The current study involved an assessment of cognitive and psychomotor effects of ***Withania somnifera*** extract in healthy human participants. In this prospective, double-blind, multi-dose, placebo-controlled, crossover study, 20 healthy male participants were randomized to receive 250 mg two capsules twice daily of an encapsulated dried aqueous extract of roots and leaves of ***Withania somnifera*** or a matching placebo for a period of 14 days. Cognitive and psychomotor performance was assessed pre-dose (day 1) and at 3 hrs post-dose on day 15 using a battery of computerized psychometric tests. After a washout period of 14 days, the subjects crossed-over to receive the other treatment for a further period of 14 days as per prior randomization schedule. Same battery of test procedures were performed to assess cognitive and psychomotor performance. Significant improvements were observed in reaction times with simple reaction, choice discrimination, digit symbol substitution, digit vigilance, and card sorting tests with ***Withania somnifera*** extract compared to placebo. However, no effect can be seen

with the finger tapping test. These results suggest that ***Withania somnifera*** extract can improve cognitive and psychomotor performance and may, therefore, be a valuable adjunct in the treatment of diseases associated with cognitive impairment.

204. Pingali, U., N. Fatima, C. U. Kumar and P. V. Kishan (2014). "**Evaluation of a highly standardized *Withania somnifera* extract on endothelial dysfunction and biomarkers of oxidative stress in patients with type 2 diabetes mellitus: a randomized, double blind, placebo controlled study.**" International Journal of Ayurveda and Pharma Research **2**(3): 22-32.

Type 2 Diabetes mellitus is a multisystem disorder with oxidative stress and endothelial dysfunction. ***Withania somnifera*** Dunal (Ashwagandha) is shown to have potent antioxidant, hypoglycemic and hypolipidemic effects in several studies. The present study was planned to compare the effect of ***Withania somnifera*** on endothelial dysfunction and biomarkers in patients with diabetes mellitus. After taking IEC approval and written informed consent, 66 eligible patients, who are on metformin therapy, were randomized to receive either one capsule of highly standardized aqueous extract of ***Withania somnifera*** 250 mg twice daily, one capsule of ***Withania somnifera*** 500 mg twice daily or Placebo for a duration of 12 weeks. Primary efficacy parameter was a change in endothelial function (measured as change in reflection index of more than 6%) performed by salbutamol challenge test at baseline and after 12 weeks of treatment. Secondary end points were change in biomarkers of oxidative stress (malondialdehyde, nitric oxide and glutathione), high sensitivity C-reactive protein and change in lipid profile. Safety lab parameters were measured, at baseline and after 12 weeks of treatment. Results show that a total of 60 patients completed the study. Twelve weeks of treatment with ***Withania somnifera*** 250 mg and 500 mg produced significant reduction in reflection index (-2.52±1.32% to -7.49±3.49%) and (-2.24±1.00% to -9.03±2.42%) respectively, suggesting improvement in endothelial function versus placebo (-2.11±1.62% to -0.81±2.86%). Similarly a significant improvement in biomarkers of oxidative stress, systemic inflammation, lipid parameters and HbA1c levels, compared to baseline and placebo, was observed with ***Withania somnifera***. All treatments are well tolerated. Conclusion is that ***Withania somnifera*** showed significant improvement in endothelial function, reduction in biomarkers of oxidative stress and systemic inflammation and can be used as a therapeutic adjunctive in patients with type 2 Diabetes mellitus.

205. Pingali, U., P. Raveendranadh and F. Nishat (2013). "**Effect of *Withania somnifera* extract on mental stress induced changes in hemodynamic properties and arterial wave reflections in healthy subjects.**" Current Topics in Nutraceutical Research **11**(4): 151-158.

Mental stress is known to contribute to the risk for hypertension and coronary atherosclerosis. ***Withania somnifera*** is well known for its anti-stress and antioxidant activity. The present study was done to assess the effect of ***Withania somnifera*** extract on acute mental stress induced changes in hemodynamics and arterial wave reflection properties in human participants. In this double-blind, placebo-controlled, randomized, crossover study, 20 healthy participants received 500 mg twice daily of an encapsulated dried aqueous extract of roots and leaves of ***Withania somnifera*** or matching placebo for 14 days with a wash out period of 14 days. Blood pressure and central arterial wave reflections were measured noninvasively using Sphygmocor

before and after a standardized mental stress test. The results demonstrated an acute effect of mental stress on blood pressure and arterial wave reflections. ***Withania somnifera*** extract produced a statistically significant decrease in aortic pressure, augmentation index, radial and aortic SBP, radial and aortic DBP and significant increase in the subendocardial viability ratio (SEVR) compared to baseline and placebo. A significant decrease in hs-CRP, MDA, serum cortisol levels is seen with ***Withania somnifera*** extract treatment compared to baseline and placebo. These results suggest that beneficial properties of ***Withania somnifera*** extract can mitigate the effects of stress and deserves further investigation in patients with associated diseases.

206. Pingali, U., N. Fatima and N. Muralidhar (2013). "**Effects of *Phyllanthus emblica* extract on endothelial dysfunction and biomarkers of oxidative stress in patients with type 2 diabetes mellitus: A randomized, double-blind, controlled study.**" Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy **6**: 275-284.

It has been reported that hyperglycemia can induce endothelial dysfunction via increased oxidative stress and that it plays a central role in the development of atherosclerosis and coronary heart disease. ***Phyllanthus emblica*** (*Emblica offcinalis*, amla) is known for its antioxidant and antihyperlipidemic activity. The present study compared the effects of an aqueous extract of *P. emblica* (highly standardized by high-performance liquid chromatography to contain low molecular weight hydrolyzable tannins, ie, emblicanin A, emblicanin B, peduncu-lagin, and punigluconin) versus those of atorvastatin and placebo on endothelial dysfunction and biomarkers of oxidative stress in patients with type 2 diabetes. Eligible patients were randomized to receive either *P. emblica* 250 mg twice daily, *P. emblica* 500 mg twice daily, atorvastatin 10 mg in the evening and matching placebo in the morning, or placebo twice daily for 12 weeks. The primary efficacy parameter was the change in endothelial function identified on salbutamol challenge at baseline and after 12 weeks of treatment. Secondary efficacy parameters were changes in biomarkers of oxidative stress (malondialdehyde, nitric oxide, and glutathione), high sensitivity C-reactive protein levels, the lipid profile, and glycosylated hemoglobin (HbA1c) levels. Laboratory safety parameters were measured at baseline and after 12 weeks of treatment. Eighty patients completed the study. Treatment with *P. emblica* 250 mg, *P. emblica* 500 mg, or atorvastatin 10 mg produced significant reductions in the reflection index (-2.25%±1.37% to -9.13%±2.56% versus -2.11%±0.98% to -10.04%±0.92% versus -2.68%±1.13% to -11.03%±3.93%, respectively), suggesting improvement in endothelial function after 12 weeks of treatment compared with baseline. There was a significant improvement in biomarkers of oxidative stress and systemic inflammation compared with baseline and placebo. Further, the treatments significantly improved the lipid profile and HbA1c levels compared with baseline and placebo. All treatments were well tolerated. Both atorvastatin and *P. emblica* significantly improved endothelial function and reduced biomarkers of oxidative stress and systemic inflammation in patients with type 2 diabetes mellitus, without any significant changes in laboratory safety parameters.

207. Portnoi, G., L.-A. Chng, L. Karimi-Tabesh, G. Koren, M. P. Tan and A. Einarson (2003). "**Prospective comparative study of the safety and effectiveness of ginger for the**

treatment of nausea and vomiting in pregnancy." American Journal of Obstetrics and Gynecology **189**(5): 1374-1377.

The primary objective of this study was to examine the safety and the secondary objective was to examine the effectiveness of ginger (***Zingiber officinale***) for nausea and vomiting of pregnancy (NVP). Pregnant women who called the Motherisk Program who were taking ginger during the first trimester of pregnancy were enrolled in the study. The women were compared with a group of women who were exposed to nonteratogenic drugs that were not antiemetic medications. The women were followed up to ascertain the outcome of the pregnancy and the health of their infants. They were also asked on a scale of 0 to10 how effective the ginger was for their symptoms of NVP. Authors were able to ascertain the outcome of 187 pregnancies. There were 181 live births, 2 stillbirths, 3 spontaneous abortions, and 1 therapeutic abortion. The mean birth weight was 3542±543 g, the mean gestational age was 39±2 weeks, and there were three major malformations. There were no statistical differences in the outcomes between the ginger group and the comparison group with the exception of more infants weighing less than 2500 g in the comparison group (12 vs 3, P ≤ .001). There were a total of 66 completed effectiveness scores with the mean score of 3.3±2.9 SD. These results suggest that ginger does not appear to increase the rates of major malformations above the baseline rate of 1% to 3% and that it has a mild effect in the treatment of NVP.

208. Post-White, J. and W. Nichols (2007). "**Randomized trial testing of QueaseEase™ essential oil for motion sickness.**" International Journal of Essential Oil Therapeutics **1**(4): 158-166.

The aim of the study was to determine preliminary evidence of efficacy of a blended essential oil product, QueaseEase™ (QE), to reduce queasiness related to motion sickness experienced on boats. This was a randomized, blinded, two group pre and post-test design with volunteer subjects with a history of motion sickness randomly assigned to either QueaseEase™ or Placebo. QueaseEase™ is a blend of ***Zingiber officinale***, *Lavandula angustifolia*, *Mentha spicata*, and *Mentha x piperita* essential oils. The placebo was distilled water, packaged in an identical carrier. Subjects were instructed to inhale the product aroma using deep breaths as often as needed and at least four times during the trip. Queasiness was assessed using a linear analogue scale of 0 (no queasiness) to 10 (worst imaginable), recorded before and after each use of the QE or placebo. Passengers also recorded symptoms, subjective responses, other methods used to manage motion sickness, and impressions of their product. Fifty-five (55) subjects participated, with 49 submitting complete data. Passengers using the QE had reduced queasiness after each use (mean change scores -0.52 to -1.14; $p < 0.05$). The QE group had less queasiness than the placebo group at one time point in the middle of the trip ($p = 0.02$). Overall reports of queasiness were low, with mean scores less than 3.5. More than 80% of the QE group would likely use the product again for motion sickness. QueaseEase™ had a significant benefit each time subjects inhaled the product. QE was more effective compared with placebo when the seas were roughest, but not significant at other times. Small sample sizes, low rates of queasiness, and various times of use may have reduced the ability to detect a difference between the groups at all time points. There were no adverse reactions

and QE showed preliminary evidence for efficacy in 55 passengers traveling on pleasure boat trips in the open ocean.

209. Prakash, B. (2011). "**Treatment of relapsed undifferentiated acute myeloid leukemia (AML-M0) with Ayurvedic therapy.**" International Journal of Ayurveda Research **2**(1): 56-59.

A 16-year-old boy was detected with acute myeloid leukemia (AML - M0) with bone marrow pathology showing 85% blasts in February 07, 1997. He received two cycles of induction chemotherapy (3+7 protocol) with daunomycin and cytosar, following which he achieved incomplete remission with bone marrow aspirate showing 14% blasts. Subsequently, the patient received two cycles of high-dose cytosine arabinoside Ara-C and achieved remission. However, his disease relapsed on August 29, 1997. Peripheral blood smear showed 6% blast cells and bone marrow showed 40% blast cells. The patient refused further chemotherapy and/or bone marrow transplant and volunteered for Ayurvedic therapy (AYT) advocated by the author from September 09, 1997. Bone marrow studies done after six months of AYT indicated that the disease was in remission. The AYT was continued for five years and stopped. Thereafter, the patient received intermittent maintenance AYT for three months in the next two years. At present, the patient is normal and healthy and has completed 12 years of disease-free survival with AYT. There were several drugs used in the treatment including Prak-20 (nineteen herbs and Mandoor Bhasma: Sunthi ***Zingiber officinale*** 13.88 mg, Maricha ***Piper nigrum*** 13.88 mg, Pippali ***Piper longum*** (fruit) 13.88 mg, Haritaki ***Terminalia chebula*** 13.88 mg, Vibhitaki ***Terminalia bellirica*** 13.88 mg, Amalaki ***Emblica officinalis*** 13.88 mg, Chitraka *Plumbago zeylanica* 13.88 mg, Musta *Cyperus rotundus* 13.88 mg, Katuki *Picrorrhiza kurroa* 13.88 mg, Devadaru *Cedrus deodara* 13.88 mg, Vidanga *Embellia ribes* 13.88 mg, Kulu/Kushta *Saussuria lappa* 13.88 mg, Haridra *Curcuma longa* 13.88 mg, Daruharidra *Berberis aristata* 13.88 mg, Danti *Baliospermum montanum* 13.88 mg, Indrayav *Holarrhena antidysentrica* (seeds) 13.88 mg, Pippali mula ***Piper longum*** 13.88 mg, Trivrit *Ipomoea turpethum* 13.88 mg, Punarnava *Boerhavia diffusa* 27.77 mg.

210. Prakash, B., P. M. Parikh and S. K. Pal (2010). "**Herbo-mineral ayurvedic treatment in a high risk acute promyelocytic leukemia patient with second relapse: 12 years follow up.**" Journal of Ayurveda and Integrative Medicine **1**(3): 215-218.

A 47 year old diabetic male patient was diagnosed and treated for high risk AML-M3 at Tata Memorial Hospital (BJ 17572), Mumbai in September 1995. His bone marrow aspiration cytology indicated 96% promyelocytes with abnormal forms, absence of lymphocytic series and myeloperoxide test 100% positive. Initially treated with ATRA, he achieved hematological remission on day 60, but cytogenetically the disease persisted. The patient received induction and consolidated chemotherapy with Daunorubicin and Cytarabine combination from 12.01.96 to 14.05.96, following which he achieved remission. However, his disease relapsed in February 97. The patient was given two cycles of chemotherapy with Idarubicine and Etoposide, after which he achieved remission. His disease again relapsed in December 97. The patient then refused more chemotherapy and volunteered for a pilot Ayurvedic study conducted by the Central Council for Research in Ayurveda and Siddha, New Delhi. The patient was treated with a proprietary Ayurvedic medicine Navajeevan, Kamadudha Rasa and

Keharuba Pisti for one year. For the subsequent 5 years the patient received three months of intermittent Ayurvedic treatment every year. The patient achieved complete disease remission with the alternative treatment without any adverse side effects. The patient has so far completed 13 years of survival after the start of Ayurvedic therapy. Navajeevan is a proprietary medicine containing Rajat Bhasma (Silver Bhasma) 1 part, Jaharmohra (Serpentine stone) 1 part, Nirvisha (*Delphinium denudatum* 1 part, Taruni, gulab (*Rosa centifolia*) 1 part, Chandan (*Santalum album*) 1 part, Gojihva *Onosma bracteatum*) 1 part, Lata kasturi (*Hibiscus abelmoschus*) 1 part. Anupan was water. Composition of Kamadudha Rasa (Anupan: Mishri) contains Mauktik Pishti Mytilus margaritiferus preparation 1 part Pravala pisti (Corallium rubrum) preparation 1 part, Mukta sukti pisti *Mytilus margaritiferus* 1 part, Kapardika bhasma Calcinated and purified *Cypraea moneta* shells 1 part, Sankha bhasma Calcinated and purified Turbinella rapa shells 1 part, Svarna gairika Calcinated and purified Ochre 1 part, Amrta satva ***Tinospora cordifolia*** extract 1 part. Composition of Keharuba Pisti: Trinakanta Mani churna – 1 partGulab arka - Q. S. (for mardana).

211. Prakash, B., S. Babu and K. Sureshkumar (2010). "**Response to Ayurvedic therapy in the treatment of migraine without aura.**" International Journal of Ayurveda Research **1**(1): 30–36.

Migraine patients who do not respond to conventional therapy, develop unacceptable side-effects, or are reluctant to take medicines resort to complementary and alternative medicines (CAM). Globally, patients have been seeking various non-conventional modes of therapy for the management of their headaches. An Ayurvedic Treatment Protocol (AyTP) comprising five Ayurvedic medicines, namely Narikel Lavan, Sootshekhar Rasa (also contains ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***) ingredients among others), Sitopaladi Churna (also contains ***Piper longum*** among others), Rason Vati (also contains ***Trikatu*** among others) and Godanti Mishran along with regulated diet and lifestyle modifications such as minimum 8 h sleep, 30-60 min morning or evening walk and abstention from smoking/drinking, was tried for migraine treatment. The duration of the therapy was 90 days. Out of 406 migraine patients who were offered this AyTP, 204 patients completed 90 days of treatment. Complete disappearance of headache and associated symptoms at completion of AyTP was observed in 72 (35.2%); mild episode of headache without need of any conventional medicines in 72 (35.2%); low intensity of pain along with conventional medicines in 50 (24.5%); no improvement in seven (3.4%) and worst pain was noted in three (1.4%) patients, respectively. In 144 (70.5%) of patients marked reduction of migraine frequency and pain intensity observed may be because of the AyTP. Though the uncontrolled open-label design of this study does not allow drawing a definite conclusion, from this observational study one can make a preliminary assessment regarding the effectiveness of this ayurvedic treatment protocol.

212. Prasad, K. P. R. C., P. G. D. Tharangani and C. N. Samaranayake (2009). "**Recurrent relapses of depression in a patient established on sertraline after taking herbal medicinal mixtures - A herb-drug interaction?**" Journal of Psychopharmacology **23**(2): 216-219.

Authors describe a patient with depression who was well controlled with sertraline monotherapy developing two relapses of depression in close temporal relationship with starting ayurvedic herbal mixtures. They discuss the possibility of a pharmacokinetic herb-drug interaction decreasing the therapeutic efficacy of sertraline leading to the relapses of depression. They speculate the herbal plant most likely to be responsible for this interaction is either ***Terminalia chebula*** or *Commiphora wighteii*.

213. Prashanth, G., M. Baghel, B. Ravishankar, S. Gupta and M. P. Mehta (2010). "**A clinical comparative study of the management of chronic renal failure with Punarnavadi compound.**" AYU **31**(2): 185-192.

India like any other country is facing a silent epidemic of chronic renal failure (CRF)- a facet of the health transition associated with industrialization partly fuelled by increase in sedentary lifestyle, low birth weight and malnutrition. Increasing figures by many folds seen is posing a difficult situation to overcome with respect to economy and health of the working and earning population of the nation. There is an urgent need to explore, highlight new interventions and modify modifiable risk factors as a basis for treatment strategies to prevent the development and progression of CRF. The present study was taken up to evaluate the role of trial formulation tab. Punarnavadi compound in the management of chronic renal failure. The compound contains Punarnava (*Boerhavia diffusa*), Gokshura (*Tribulus terrestris*), Varuna (*Crataeva nurvala*), Shigru (*Moringa olifera*), Kusha (*Desmostachya bipinnata*), Kandekshu (*Saccharum officinalum*), Guduchi (***Tinospora cordifolia***), Shatavari (*Asparagus racemosus*), Shilajit (Asphaltum panjabiunum). This was an open clinical comparative study in controlled circumstances wherein 67 patients were studied for two months in three groups- Group A (allopathic control), Group B (ayurvedic control) and Group C (ayurvedic test). It was a multi-centric study; patients were registered from Anandababa charitable dialysis centre, Jamnagar, Kayachikitsa O.P.D. of I.P.G.T. and R.A. Jamnagar and P. D. Patel Ayurveda hospital, Nadiad. Results were assessed on 15 parameters using Students (paired) 't' test. Group A patients showed comparatively better results in eight parameters- weight, platelet count, serum urea, serum uric acid, serum sodium, potassium, chloride and total proteins. Parameter Hemoglobin% showed better results in Group B patients and in Group C patients comparatively better results in six parameters viz.- quality of life (breathlessness, weakness, general functional capacity), total count, serum creatinine and serum calcium - were observed. Throughout the study, trial drug tab. Punarnavadi compound did not show any adverse drug reaction. The results of this study will help in developing a cheap and safe treatment for the management of CRF.

214. Pratoomsoot, C., R. Sruamsiri, P. Dilokthornsakul and N. Chaiyakunapruk (2015). "**Quality of reporting of randomised controlled trials of herbal interventions in ASEAN plus six countries: A systematic review.**" PLoS ONE **10**(1): DOI: 10.1371/journal.pone.0108681

Many randomised controlled trials (RCTs) of herbal interventions have been conducted in the ASEAN Communities. Good quality reporting of RCTs is essential for assessing clinical significance. Given the importance ASEAN placed on herbal medicines, the reporting quality of RCTs of herbal interventions among the ASEAN

Communities deserved a special attention. Study was conducted to systematically review the quality of reporting of RCTs of herbal interventions conducted in the ASEAN Plus Six Countries. Searches were performed using PubMed, EMBASE, The Cochrane Library, and Allied and Complementary Medicine (AMED), from inception through October 2013. These were limited to studies specific to humans and RCTs. Herbal species search terms were based on those listed in the National List of Essential Medicines [NLEM (Thailand, 2011)]. Studies conducted in the ASEAN Plus Six Countries, published in English were included. Seventy-one articles were identified. Thirty (42.25%) RCTs were from ASEAN Countries, whereas 41 RCTs (57.75%) were from Plus Six Group. Adherence to the recommended CONSORT checklist items for reporting of RCTs of herbal interventions among ASEAN Plus Six Countries ranged from 0% to 97.18%. Less than a quarter of the RCTs (18.31%) reported information on standardisation of the herbal products. However, the scope of interventions of interest was limited to those developed from 20 herbal species listed in the NLEM of Thailand. The present study highlights the need to improve reporting quality of RCTs of herbal interventions across ASEAN Plus Six Communities.

215. Pratte, M. A., K. B. Nanavati, V. Young and C. P. Morley (2014). "**An alternative treatment for anxiety: a systematic review of human trial results reported for the ayurvedic herb ashwagandha (*Withania somnifera*).**" Journal of Alternative and Complementary Medicine **20**(12): 901-908.

Objective was to assess existing reported human trials of ***Withania somnifera*** (WS; common name, ashwagandha) for the treatment of anxiety. Design: Systematic review of the literature, with searches conducted in PubMed, SCOPUS, CINAHL, and Google Scholar by a medical librarian. Additionally, the reference lists of studies identified in these databases were searched by a research assistant, and queries were conducted in the AYUSH Research Portal. Search terms included "ashwagandha," "***Withania somnifera***," and terms related to anxiety and stress. Inclusion criteria were human randomized controlled trials with a treatment arm that included WS as a remedy for anxiety or stress. The study team members applied inclusion criteria while screening the records by abstract review. Intervention: Treatment with any regimen of WS. Outcome measures: Number and results of studies identified in the review. Results: Sixty-two abstracts were screened; five human trials met inclusion criteria. Three studies compared several dosage levels of WS extract with placebos using versions of the Hamilton Anxiety Scale, with two demonstrating significant benefit of WS versus placebo, and the third demonstrating beneficial effects that approached but did not achieve significance (p=0.05). A fourth study compared naturopathic care with WS versus psychotherapy by using Beck Anxiety Inventory (BAI) scores as an outcome; BAI scores decreased by 56.5% in the WS group and decreased 30.5% for psychotherapy (p0.0001). A fifth study measured changes in Perceived Stress Scale (PSS) scores in WS group versus placebo; there was a 44.0% reduction in PSS scores in the WS group and a 5.5% reduction in the placebo group (p0.0001). All studies exhibited unclear or high risk of bias, and heterogenous design and reporting prevented the possibility of meta-analysis. Conclusions: All five studies concluded that WS intervention resulted in greater score improvements (significantly in most cases) than placebo in outcomes on anxiety or stress scales. Current evidence should

be received with caution because of an assortment of study methods and cases of potential bias.

216. Purandare, H. and A. Supe (2007). "**Immunomodulatory role of *Tinospora cordifolia* as an adjuvant in surgical treatment of diabetic foot ulcers: A prospective randomized controlled study.**" Indian Journal of Medical Sciences **61**(6): 347-355.

Chronic diabetic patients with wounds have deficient growth factors and impaired local and systemic cellular immunity. Treatment with growth factors is expensive with risk of infection transmission, and these factors may not achieve optimum wound concentration. Authors evaluated the role of generalized immunomodulation in diabetic ulcers by using ***Tinospora cordifolia*** as an adjuvant therapy and studied its influence on parameters/determinants of healing, on bacterial eradication and on polymorphonuclear phagocytosis. It was a prospective double-blind randomized controlled study lasting for over 18 months in 50 patients. The ulcer was classified by wound morphology and severity with Wound Severity Score (Pecoraro-Reiber system). Mean ulcer area, depth and perimeter were measured and swabs taken for culture. Blood was collected to assess polymorphonuclear % phagocytosis (PMN function by Lehrer-Cline C. albicans method). Medical therapy, glycemic control, debridement, wound care were optimized. At 4 weeks, parameters were reassessed. PMN function was reviewed at 3 months. Results and Analysis: Forty-five patients completed the trial: study group - 23 (M:F = 17:1; mean age = 56.3 years; mean ulcer duration = 21.1 days); control group 22 (M:F = 19:3; mean age = 56.3 years; mean ulcer duration = 30.4 days). Net improvement was seen in 17 patients (73.9%) in the study group; while in the control group, in 13 patients (59.1%); P = 0.292. Specific parameters included rate of change of ulcer area - cm 2 /day (study - 0.15; control - 0.07; P = 0.145); rate of change of ulcer perimeter - mm/day (study - 0.09; control = - 0.07; P = 0.089); change of depth - mm (study - 2.2; control - 1.4; P = 0.096); change of wound score (study - 14.4; control - 10.6; P = 0.149); total number of debridements (study - 1.9; control - 2.5; P = 0.03) and change in % phagocytosis (study - 3.9; control - 2.3; P = 0.048). Diabetic patients with foot ulcers on *T. cordifolia* as an adjuvant therapy showed significantly better final outcome with improvement in wound healing. Reduced debridements and improved phagocytosis were statistically significant, indicating beneficial effects of immunomodulation for ulcer healing.

217. Rai, M. and S. Gupta (1967). "**Experimental evaluation of *Tinospora cordifolia* (guduchi) for dissolution of urinary calculi.**" J Res Ind Med **2**(1): 115.

The water extract of the stem of ***Tinospora cordifolia*** was experimentally evaluated for dissolution of urinary calculi. It was found effective.

218. Rahnama, P., H. Fallah Huseini, H. Mohammadi, M. Modares, K. Khajavi Shojaee, M. Askari and P. Mozayani (2010). "**The effects of *Zingiber officinale* R. on primary dysmenorrhea.**" Journal of Medicinal Plants **9**(36): 81-86+209.

Prevalence of dysmenorrhea and its importance for women life as well as side effects of non steroid anti inflammatory drug used for its treatment increases the tendency for alternative complementary, and herbal therapy. This study was carried out to determine the effect of ***Zingiber officinale*** R. on primary dysmenorrheal on students residing in Dormitories' Shahed University. This clinical trial was performed on 78

unmarried students, average 21 years old with primary dysmenorrhea residing in Dormitories' Shahed University. Subjects were selected through a questionnaire which included demographic and menstrual cycle characteristics and graded of dysmenorrhea. Graded of dysmenorrhea were determined by verbal multidimensional scoring system and subjects who were graded moderate and severe dysmenorrhea were randomly allocated into two groups that received the *Zingiber* capsule and the placebo capsule. The subjects in Zingiber group received the 500 mg zingiber powders in capsules three times a day for three days and placebo group received 500 mg placebo capsule similarly from a day of starting of menstruation. Severity and duration of dysmenorrheal pain were determined in both groups and compared to each other. Results: Results indicate that demographic characteristics (age, BMI and menstrual status) were similar between two groups before treatments. Severity and duration of dysmenorrhea in Zingiber group deceased significantly ($p<0.01$ and $p<0.021$ respectively) at the end of the study compared to placebo group. Administration of *zingiber* 500 mg t.i.d decreases pain and duration of primary dysmenorrhea without any obvious adverse effects. The investigation for accurate effective doses of Zingiber and its adverse effect on long term administration is recommended.

219. Raj, A., G. R., U. Shailaja, P. Debnath, S. Banerjee and P. N. Rao (2015). "**Exploratory studies on the therapeutic effects of Kumarabharana Rasa in the management of chronic tonsillitis among children at a tertiary care hospital of Karnataka.**" Journal of Traditional and Complementary Medicine: doi:10.1016/j.jtcme.2014.1011.1031.

The effect of an Ayurvedic poly-herbo-mineral formulation Kumarabharana Rasa (KR) in the management of chronic tonsillitis (Tundikeri) in children has been assessed in this study. This clinical study was a double-arm study with a pre- and post-test design at the outpatient level in a tertiary Ayurveda hospital attached to a teaching institute located in district headquarters in Southern India. Patients (n = 40) with chronic tonsillitis satisfying diagnostic criteria and aged between 5 and 10 years were selected from the outpatient Department of Kaumarbhritya, SDM College of Ayurveda and Hospital, Hassan. Among them, 20 patients were treated with Kumarabharana rasa (tablet form) at a dose of 500 mg once daily for 30 days (Group A). Kumarabharana Rasa is a compound drug comprising Bhasmas (purified calx) of Swarna (gold), Rajata (silver), Pravala (coral) and Churna (powder) of Yastimadhu (*Glycyrrhiza glabra* Linn.), Amlaki (***Emblica officinalis*** Gaertn.), Ashwagandha (***Withania somnifera*** Dunal.), Sunthi (***Zingiber officinale*** Rosc.), Pippali (***Piper longum*** Linn.), Haritaki (***Terminalia chebula*** Retz.), Vacha (*Acorus calamus* Linn.). All these drugs were processed with Swarasa (extract juice) of Guduchi (***Tinospora cordifolia*** Miers ex Hook. F. & Thoms), Brahmi (*Centella asiatica* Linn.), and Tulsi (*Ocimum tenuiflorum* Linn.) separately then prepared in tablet form. The other 20 patients were treated with Godhuma Vati (placebo) at a dose of 500 mg once daily for 30 days (Group B). In both groups, Madhu was the Anupana advised. After completion of 30 days of treatment, the patients were assessed on the following day and another investigation took place 15 days later. Statistically significant effects (p < 0.05) in the reduction of all signs and symptoms of chronic tonsillitis after KR treatment were observed. These results indicate that Kumarabharana Rasa has an ameliorative effect in reducing the signs and symptoms of chronic tonsillitis.

220. Ramachandran, A. P., S. M. Prasad, U. Prasad and S. Jonah (2010). "**A comparative study of Kaishora Guggulu and Amrita Guggulu in the management of Utthana Vatarakta.**" AYU **31**(4): 410-416.

Vatarakta (Grouty Arthritis) is the major example of Vata vyadhi, caused due to avarana pathology. The scenario of Utthana Vatarakta occurred owing to the margavarana pathology, which can very well be correlated with atherosclerotic peripheral arterial disease. The literature enlists a number of Guggulu prayogas in the management of Vatarakta. An additional cavernous revise was indispensable to bring out the precise outcome of these products. Keeping these visions in mind, the particular comparative study was performed with Kaishora guggulu and Amrita guggulu, which are explained in the same context. This is a single-blind comparative clinical study with a pre-test and post-test design, wherein a minimum of 30 patients of either sex, suffering from Utthana Vatarakta, in an age limit of 16 to 70 years, were selected and randomly categorized into two groups. The 15 patients of group A were treated with oral administration of Tab Kaishora guggulu 1 g thrice a day and the group B patients with Tab Amrita guggulu of the same dose pattern with anupana of lukewarm water. Kaishora Guggulu consists of the following ingredients: Haritaki Fruit (***Terminalia chebula***), Vibhitaki Fruit (***Terminalia bellirica***), Amalaki Fruit (***Emblica officinalis***), Guduchi Stem (***Tinospora cordifolia***), Ginger Root (***Zingiber officinale***), Pippali Fruit (***Piper longum***), Black Pepper Fruit (***Piper nigrum***), Vidanga (*Embelia ribes*), Danti Root (*Baliospermum montanum*), Trivruth Root (*Operculina turpethum*), Guggulu Resin (*Commiphora mukul*). The therapeutic effect of the treatment was assessed in both the groups based on specific subjective and objective parameters. The results obtained were analyzed statistically in both the groups and the comparative effect was assessed using the unpaired "t" -test. In the present study, 80% of the patients from both the groups had madhumeha (Diabetes mellitus), shonita mada (Hypertension) or both. Fifty percent of the patients in group A and nearly 60% of the patients in group B, suffering from Utthana Vatarakta, had the habit of smoking. In both the groups, a statistically significant improvement was observed in all the criteria of assessment. The outcome of the study revealed an identical therapeutic efficacy of Kaishora guggulu and Amrita guggulu in Utthana Vatarakta. The use of Kaishora guggulu or Amrita guggulu as shamana Aushadhas was a perfect selection in the management of rakta margavaranajanya Utthana Vatarakta.

221. Ramazani, M., M. R. Hamidi, A. A. Moghaddamnia, N. Ramazani and N. Zarenejad (2013). "**The prophylactic effects of Zintoma and Ibuprofen on post-endodontic pain of molars with irreversible pulpitis: A randomized clinical trial.**" Iranian Endodontic Journal **8**(3): 129-134.

Post endodontic pain is often linked to the inflammatory process as well as additional central mechanisms. The purpose of the present double-blind randomized clinical trial study was to compare the prophylactic effects of a derivative of ***Zingiber officinale***, Zintoma, and Ibuprofen on post endodontic pain of molars with irreversible pulpitis. Materials and Methods: The post endodontic pain of 72 enrolled patients suffering from irreversible pulpitis was assessed after prophylactic use of 400 mg Ibuprofen, 2 gr Zintoma and placebo. Using the Heft-Parker Visual Analogue

Scale, the patients recorded their perceived pain before taking the medicament (baseline), immediately after and also at 4, 8, 12, 24, 48, and 72 h post one-visit endodontic treatment. The statistical analysis was done using Kruskal-Wallis, Mann-Whitney, and Freedman tests (P<0.05). Results: At all times, there was significant difference between the Ibuprofen and Zintoma (P<0.05) and also between the Ibuprofen and placebo (P<0.05). However, there was no significant difference between Zintoma and the placebo in any of time intervals (P>0.05). No side effects were observed. Conclusion: The obtained results of the trial revealed that prophylactic use of 2 gr Zintoma is not an effective pain relieving agent.

222. Raut, A., L. Bichile, A. Chopra, B. Patwardhan and A. Vaidya (2013). "**Comparative study of amrutbhallataka and glucosamine sulphate in osteoarthritis: Six months open label randomized controlled clinical trial.**" Journal of Ayurveda and Integrative Medicine **4**(4): 229-236.

AmrutBhallatak (ABFN02), a 'rasayana' drug from Ayurveda is indicated in degenerative diseases and arthritis. The formulation has two main ingredients viz. Bhallatak (*Semecarpus anacardium*) and Guduchi ((***Tinospora cordifolia***). Both these ingredients are reputed as 'rasayana' (rejuvenative/reparative) drugs in Ayurvedic literature. Objective: To evaluate safety and efficacy of ABFN02 in osteoarthritis (OA) and compare it with Glucosamine sulphate (GS) Materials and Methods: This was a r andomized open comparative study. Ambulant OPD patients of OA knees (n = 112) were enrolled for 24 weeks. Tablets (750mg each) of GS and ABFN02 were matched. Three groups of patients: (A) GS, one tablet × twice/day × 24 weeks. (B) ABFN02, incremental pulse dosage (one tablet x twice/day × two weeks, two tablets × twice/day × two weeks, three tablets × twice/day × two weeks), two such cycles of drug and non-drug phases alternately for six weeks each (C) ABFN02 continuous dosage akin to GS. Pain visual analogue score (Pain-VAS) and Western Ontario and Mc-Master University Osteoarthritis Index (WOMAC) were the primary outcome measures. Secondary outcome measures were Health assessment questionnaire (HAQ), paracetamol consumption, 50 feet walking, physician and patient global assessment, knee stiffness, knee status, urinary CTX II, serum TNFa-SRI, SRII and MRI knee in randomly selected patients. ABFNO2 and GS demonstrated, adherence to treatment 87.75% and 74.3%, reduction in Pain-VAS at rest 61.05% and 57.1%, reduction in pain-VAS on activity 57.4% and 59.8%, WOMAC score drop 62.8% and 59.1% respectively. Secondary outcome measures were comparable in all groups. Safety measures were also comparable. No serious adverse events reported. However, asymptomatic reversible rise in liver enzymes was noted in the ABFNO2 group. The incidence of methotrexate induced increases in serum alanine aminotransferase (ALT) is approximately 14%, while the incidence of increases into the abnormal range of aspartate aminotransferase (AST) is 8% in non-malignant diseases on oral use and the abnormality of liver enzymes usually resolves within one month of discontinuation. [ABFN02 has significant activity in OA; the formulation needs further investigation.

223. Raut, A. A., N. N. Rege, F. M. Tadvi, P. V. Solanki, K. R. Kene, S. G. Shirolkar, S. N. Pandey, R. A. Vaidya and A. B. Vaidya (2012). "**Exploratory study to evaluate tolerability, safety,**

and activity of Ashwagandha (*Withania somnifera*) in healthy volunteers." Journal of Ayurveda and Integrative Medicine **3**(3): 111-114.

Ashwagandha (***Withania somnifera***) (WS), a "rasayana" drug, is recommended for balavardhan and mamsavardhan. The study was intended to evaluate dose-related tolerability, safety, and activity of WS formulation in normal individuals. The design was prospective, open-labeled, variable doses in volunteers. Eighteen apparently healthy volunteers (12M:6F, age:18-30 years, and BMI: 19-30) were enrolled. After baseline investigations, they received WS capsules (Rx) (aqueous extract, 8:1) daily in two divided doses with increase in daily dosage every 10 days for 30 days (750 mg/day x10 days, 1 000 mg/day x 10 days, 1 250 mg/day x 10 days). Volunteers were assessed for symptoms/signs, vital functions, hematological and biochemical organ function tests. Muscle activity was measured by hand grip strength, quadriceps strength, and back extensor force. Exercise tolerance was determined using cycle ergometry. Lean body weight and fat% were computed from skin fold thickness measurement. Adverse events were recorded, as volunteered by the subjects. Repeated measures ANOVA, McNemar's test, and paired t test were employed. All but one volunteer tolerated WS without any adverse event. **One volunteer showed increased appetite, libido, and hallucinogenic effects with vertigo at the lowest dose and was withdrawn from study.** In six subjects, improvement in quality of sleep was found. Organ function tests were in normal range before and after the intervention. Reduction in total-and LDL-cholesterol and increase of strength in muscle activity was significant. Total body fat percentage showed a reduction trend. WS, in escalated dose, was tolerated well. The formulation appeared safe and strengthened muscle activity. In view of its traditional Rasayana use, further studies are planned to evaluate potential of this drug in patients of sarcopenia.

224. Rawal Prof, R. C., P. Gandhi, T. B. Singh Prof and K. H. H. V. S. S. Narasimha Murthy (2013). "**Clinical evaluation of hairbac tablet and oil in the management of diffuse hair loss: An open clinical study.**" International Journal of Research in Ayurveda and Pharmacy **4**(4): 564-569.

Hair is an important component of the body derived from ectoderm of skin. Keratin is the main component of hair fibers. Hair has great psycho-social significance for persons. The average growth rate in a normal scalp is 0.41 mm per day but lower growth rate is observed among aged persons and chronic disease persons. Hair loss is a most common problem among men and women of all age groups and it is a socially and psychologically distressing also. Its severity varies from a small bare patch to a more diffuse and obvious pattern. Diffuse hair loss may occur at any age and gender. It affects the whole scalp. Management of hair fall is extremely complex. Treatments for the various forms are available but alopecia has limited success. As a general rule, it is easier to maintain remaining hair than it is to re-grow; however, the success rate is very less with unwanted adverse effects. There are claims that poly herbal formulations are giving promising results. So, a poly herbal formulation 'Hairbac' tablet and oil, is evaluated for its safety and efficacy in diffuse hair loss. The subjective parameters used for assessment were Hair Texture, Hair Density/cm sq area and Hair Loss. The beneficial effects of Hairbac Tablets and Oil assessed in the context of hair texture, density /1cm2 and hair loss among females suffering with diffuse hair fall showed highly significant improvement without any adverse effects

assessed by the respondents. Drugs contained in tablet and oil include *Bacopa monnieri* extract; *Eclipta prostrata* extract; ***Emblica officinalis*** extract; hairbac; herbaceous agent; *Indigofera tinctoria* extract; *Nardostachy jatamansi* extract; oil; *Phyllanthus niruri* extract; plant extract; *Santalum album* extract; and *Spirulina* extract among others.

225. Rege, N., R. D. Bapat, R. Kori, N. K. Desai and S. Dahanukar (1993). "**Immunotherapy with *Tinospora cordifolia*: A new lead in the managemnt of obstructive jaundice.**" Indian Journal of Gastroenterology **12**(1): 5-8.

Immunosuppression associated with deranged hepatic function and sepsis results in poor surgical outcome in extrahepatic obstructive jaundice. The effect of an ayurvedic agent, ***Tinospora cordifolia*** (TC), which has been shown to have hepatoprotective and immunomodulatory properties in experimental studies, on surgical outcome in patients with malignant obstructive jaundice was evaluated. Thirty patients were randomly divided into two groups, matched with respect to clinical features, impairment of hepatic function (as judged by liver function tests including antipyrine elimination) and immunosuppression (phagocytic and killing capacities of neutrophils). Group I received conventional management, ie vitamin K, antibiotics and biliary drainage; Group II received ***Tinospora cordifolia*** (16 mg/kg/day orally) in addition, during the period of biliary drainage. Hepatic function remained comparable in the two groups after drainage. However, the phagocytic and killing capacities of neutrophils normalized only in patients receiving ***Tinospora cordifolia*** (28.2 +/- 5.5% and 29.47 +/- 6.5% respectively). Post-drainage bactobilia was observed in 8 patients in Group I and 7 in Group II, but clinical evidence of septicemia was observed in 50% of patients in Group I as against none in Group II ($p < 0.05$). Post-operative survival in Groups I and II was 40% and 92.4% respectively ($p < 0.01$). ***Tinospora cordifolia*** appears to improve surgical outcome by strengthening host defenses.

226. Rotman-Pikielny, P., R. Ness-Abramof, G. Charach, A. Roitman, R. Zissin and Y. Levy (2014). "**Efficacy and Safety of the Dietary Supplement DBCare® in Patients With Type 2 Diabetes Mellitus and Inadequate Glycemic Control.**" Journal of the American College of Nutrition **33**(1): 55-62.

Aims: DBCare® (Ace Continental Exports Inc., London, UK) is a traditional Indian herbal food supplement marketed as an antidiabetes remedy. Among other herbs, it also contains ***Tinospora cordifolia***. This study evaluated the efficacy and safety of DBCare in patients with inadequately controlled type 2 diabetes mellitus (T2DM) despite oral hypoglycemic treatment. Methods: A 12-week randomized double-blind placebo-controlled trial was conducted. Patients with T2DM on oral hypoglycemic agents with HbA1C > 7.0% were randomized to receive DBCare or placebo tablets. Results: Thirty-five patients (20 male/15 female; mean age 61.2 ± 7.6 years), with a mean baseline HbA1C of 7.9% ± 0.6%, received DBCare (N = 18) or placebo (N = 17). During the study period, HbA1C declined 0.4 ± 0.7% in the DBCare® group and 0.2% ± 0.8% in the placebo group ($p = 0.806$). No significant changes occurred in fasting plasma glucose, lipid profile, or homeostasis model assessment throughout the study or in body mass index, waist circumference, or blood pressure values. Hypoglycemic episodes (glucose < 70 mg/dL) were more frequent in the treatment group (7 vs 1, p

= 0.043), necessitating a decrease in other hypoglycemic medications in 2 patients. DBCare was generally well tolerated, with mild side effects that were not different from those of the placebo group. Conclusions: This preliminary study did not demonstrate that DBCare was efficacious in improving glycemic control in inadequately controlled patients with T2DM on oral hypoglycemics. A trend toward improved glycemic control was noted in the DBCare group, which correlates with more frequent hypoglycemic episodes. Further studies are needed to elucidate DBCare's hypoglycemic effect in patients with T2DM in general and in specific clinical settings, such as HbA1C ≥ 8%, short (≤10-year) duration of diabetes, or young age in particular.

227. Roy, K. (2015). "***Tinospora cordifolia* stem supplementation in diabetic dyslipidemia: an open labelled randomized controlled trial.**" Functional Foods in Health and Disease **5**(8): 265-274.

Medicinal plants are powerful health promoting nutritional agents. Among the vast library of medicinal plants ***Tinospora cordifolia*** (Willd.) has been meagrely explored. It belongs to the family Menispermaceae and is a rich source of alkaloid and terpenes. It has hepatoprotective, antioxidant, immunostimulatory, hyperlipidemic, anticancer and antidiabetic properties. The stem contains berberine, palmatine, tembetarine, magnoflorine, tinosporin, tinocordifolin. The stem starch is highly nutritive and digestive. In modern medicine it is called the magical rejuvenating herb owing to its properties to cure many diseases. The stem contains higher alkaloid content than the leaves because of which it is approved for medicinal usage. With a host of phytochemical properties present in the stem, it may hold potential to manage dyslipidemia and dysglycemia, which otherwise has been proven only in pre-clinical studies. Objective: To study the impact of ***Tinospora cordifolia*** stem supplementation on the glycemic and lipemic profile of subjects with diabetic dyslipidemia. Type 2 diabetics with dyslipidemia on oral hypoglycemic agents were enrolled. Baseline data on medical history, family history of lifestyle diseases, duration of diabetes diagnosis, drug profile, anthropometric data, dietary data and physical activity data was obtained along with a fasting blood sample for estimating high sensitivity C reactive protein (hs-CRP), hepatic, renal, lipid profile and glycated hemoglobin. The participants were randomized into either of the two groups; intervention group (n=29) received 250mg of encapsulated mature stem of ***Tinospora cordifolia*** pre meal twice a day along with prescribed dyslipidemic agent and control group (n=30) only on dyslipidemic agents for a period of 60 days. After 60 days all the parameters were re-assessed to analyse the impact of the intervention. Results: Majority of the subjects in both the arms were in the 50-60 years age bracket with a similar duration of diabetes, disease and drug profile. ***Tinospora cordifolia*** supplementation led to a significant decline in waist circumference (94.7 to 94.2cm, P 0.004), hip circumference (99.9 to 9.5cm, P 0.004), waist stature ratio (0.594 to 0.591, P 0.004) and systolic blood pressure (132.6 to 127.1mmHg, P 0.0017) vs. significant decline in hip circumference (100.02 to 99.7cm, P 0.01) and systolic blood pressure (134.5 to 130.1mmHg, P 0.0013) in controls. The intervention brought about a significant decline in hs-CRP (4.6 to 2.8mg/l, P 0.0007) and the prevalence of hs-CRP>3mg/l declined from 65.5% to 37.9% (P 0.037). Renal and hepatic parameters remained in the normal range. Decline in HbA1c, although non-significant, was more

evident in the intervention arm (7.7 to 7.5%, P 0.09) than the controls (7.9 to 7.81%, P 0.52). Intervention led to significant reductions in total cholesterol, low density lipoprotein, triglycerides and very low density lipoprotein and among controls too, but of lesser intensity. The number of dyslipidemic features declined by 28.6% (P 0.0036) in the intervention arm and by 19.4% in controls (P 0.020). The prevalence of metabolic syndrome decreased by 13.73% from 68.9% to 55.17% in the intervention arm and reduced by 6.7% from 56.7% to 50% among controls.

228. Ryan, J. L., C. E. Heckler, J. A. Roscoe, S. R. Dakhil, J. Kirshner, P. J. Flynn, J. T. Hickok and G. R. Morrow (2012). "**Ginger (*Zingiber officinale*) reduces acute chemotherapy-induced nausea: A URCC CCOP study of 576 patients.**" Supportive Care in Cancer **20**(7): 1479-1489.

Despite the widespread use of antiemetics, nausea continues to be reported by over 70% of patients receiving chemotherapy. In this double blind, multicenter trial, authors randomly assigned 744 cancer patients to four arms: 1) placebo, 2) 0.5 g ginger, 3) 1.0 g ginger, or 4) 1.5 g ginger. Nausea occurrence and severity were assessed at a baseline cycle and the two following cycles during which patients were taking their assigned study medication. All patients received a 5-HT3 receptor antagonist antiemetic on Day 1 of all cycles. Patients took three capsules of ginger (250 mg) or placebo twice daily for 6 days starting 3 days before the first day of chemotherapy. Patients reported the severity of nausea on a 7-point rating scale ("1"="Not at all Nauseated" and "7"="Extremely Nauseated") for Days 1-4 of each cycle. The primary outcomes were to determine the dose and efficacy of ginger at reducing the severity of chemotherapy-induced nausea on Day 1 of chemotherapy. Results A total of 576 patients were included in final analysis (91% female, mean age = 53). Mixed model analyses demonstrated that all doses of ginger significantly reduced acute nausea severity compared to placebo on Day 1 of chemotherapy ($p=0.003$). The largest reduction in nausea intensity occurred with 0.5 g and 1.0 g of ginger ($p=0.017$ and $p=0.036$, respectively). Anticipatory nausea was a key factor in acute chemotherapy-induced nausea ($p<0.0001$). Ginger (***Zingiber officinale***) supplementation at a daily dose of 0.5 g-1.0 g significantly aids in reduction of the severity of acute chemotherapy-induced nausea in adult cancer patients.

229. Saenghong, N., J. Wattanathorn, S. Muchimapura, T. Tongun, N. Piyavhatkul, C. Banchonglikitkul and T. Kajsongkram (2012). "***Zingiber officinale* improves cognitive function of the middle-aged healthy women.**" Evidence-based Complementary and Alternative Medicine **2012**, 383062. doi: 10.1155/2012/383062.

The development of cognitive enhancers from plants possessing antioxidants has gained much attention due to the role of oxidative stress-induced cognitive impairment. Thus, this study aimed to determine the effect of ginger extract, or ***Zingiber officinale***, on the cognitive function of middle-aged, healthy women. Sixty participants were randomly assigned to receive a placebo or standardized plant extract at doses of 400 and 800mg once daily for 2 months. They were evaluated for working memory and cognitive function using computerized battery tests and the auditory oddball paradigm of event-related potentials at three different time periods: before receiving the intervention, one month, and two months. Study found that the ginger-treated groups had significantly decreased P300 latencies, increased N100

and P300 amplitudes, and exhibited enhanced working memory. Therefore, ginger is a potential cognitive enhancer for middle-aged women.

230. Saha, A., B. Bhatia and K. S. Kulkarni (2002). "**Evaluation of the Efficacy of Mentat in Children with Learning Disability: A Placebo-Controlled Double-Blind Clinical Trial.**" Neurosciences Today **6**(3): 184-188.

A double blind placebo controlled clinical trial was conducted to evaluate the efficacy of Mentat in children with learning disability. The study was carried out in 100 students with learning disability belonging to class VI to XI students aged between 11-16 years who had secured ≤45% marks in the annual examination, had potential for performing academically better and had IQ ≥90 and also who did not have any visual or auditory problem. Children with space occupying lesion, genetic disorder, renal failure preceding for the last 6 months, with recent cerebrovascular episodes and those suffering from non-concomitant severe illness necessitating other treatment and children who are not co-operative. These children were further divided into four groups: Group N (Placebo), Group P (Drug), Group S/F (Placebo) and Group R/G (Drug). The assessment of cognitive functions was done with Malin's intelligence scale of Indian children and Bender visual motor Gestalt test. Mentat was administered orally for 6 months, and results evaluated after 6 months. Children receiving Mentat performed significantly better on full scale and performance. An improvement in the attention and concentration as well as increase in their attention span was seen. They had better sequential ability. No child showed any behavior and speech abnormality during the trial. On the basis of the above observations it may be concluded that Mentat improved attention and concentration in learning disability in school children. Mentat contains herbs like *Bacopa monnieri* (Brahmi), *Centella asiatica* (Mandukaparni), ***Withania somnifera*** (Ashwagandha), *Nardostachys jatamansi* (Jatamansi), *Acorus calamus* (Vacha), ***Tinospora cordifolia*** (Guduchi), ***Emblica officinalis*** (Amalaki), *Terminalia arjuna* (Arjuna) and others, which act as nervine tonics, correct impaired mental function, prevent loss of memory and help in improving intelligence and memory.

231. Sahib, A. S. (2013). "**Treatment of irritable bowel syndrome using a selected herbal combination of Iraqi folk medicines.**" Journal of Ethnopharmacology **148**(3): 1008-1012.

Mentha longifolia, *Cyperus rotundus* and ***Zingiber officinale*** are widely used in Iraqi traditional medicine for the treatment of multiple gastrointestinal diseases. The aim of this study was to examine the effectiveness of a combination of three herbal agents that are widely used in folk medicine in Iraq for the treatment of patients with irritable bowel syndrome (IBS). A prospective randomised clinical study was carried out on 40 patients of both sexes between 25 and 60 years of age who had been diagnosed with IBS for 5-10 years. The patients were allocated to one of two groups, each consisting of 20 patients. Group A was treated with mebeverine, and Group B was treated with a capsule containing a combination of the following three herbs prepared as fine powders: Mentha longifolia, Cyperus rotundus and ***Zingiber officinale***. IBS symptoms were assessed before and after 8 weeks of treatment. Treatment of IBS patients with the herbal combination resulted in improvements in all of their IBS symptoms after 8 weeks, as revealed by increase in their individual symptom scores and in their mean total improvement percentages. These results

were comparable to those produced by the standard agent mebeverine. Patients with IBS showed significant improvements in their IBS symptoms after 8-weeks of treatment with the herbal combination and did not report any adverse effects during their treatment. These results support the efficacy and safety of the herbal combination for the treatment of IBS.

232. Sai, K. S. and N. Srividya (2002). "**Blood glucose lowering effect of the leaves of *Tinospora cordifolia* and *Sauropus androgynus* in diabetic subjects.**" Journal of Natural Remedies **2**(1): 28-32.

The effect of the aqueous leaf digest (10g/200ml water) of the two experimental plants on post-prandial blood glucose levels was determined separately, in non-insulin dependent diabetic (NIDDM) subjects using the method of glucose tolerance test (GTT). The effect was compared with the glycemic response elicited by the control (glucose=50g) and the hypoglycaemic activity was evaluated in terms of glycemic index (GI) score. Results: The rise in the blood glucose levels of the subjects administered with the experimental samples were lower than the levels observed after feeding glucose control, with the glucose levels reverting back to fasting levels after 2 h. of administration in experimental groups. The GI scores of *T. cordifolia* (GI=39) and *S. androgynus* (GI=55) were significantly lower than that of glucose control (GI=100). *T. cordifolia* is found to exhibit a significant ability to reduce blood sugar levels in human subjects. This corroborates with the results of earlier animal studies and its use as an anti-diabetic agent in ayurvedic medical system. The hypoglycaemic activity of *S. androgynus* indicated in the present study warrants investigation into the compounds/extracts with anti-diabetic activity.

233. Sandhu, J. S., B. Shah, S. Shenoy, S. Chauhan, G. Lavekar and M. Padhi (2010). "**Effects of *Withania somnifera* (Ashwagandha) and *Terminalia arjuna* (Arjuna) on physical performance and cardiorespiratory endurance in healthy young adults.**" International Journal of Ayurveda Research 1(3): 144–149.

Several medicinal plants have been described to be beneficial for cardiac ailments in Ayurveda like Ashwagandha and Arjuna. Ashwagandha-categorised as Rasayanas, and described to promote health and longevity and Arjuna primarily for heart ailments. coronary artery disease, heart failure, hypercholesterolemia, anginal pain and can be considered as a useful drug for coronary artery disease, hypertension and ischemic cardiomyopathy. There are no scientific clinical studies showing effect of both these drugs on exercise performance after regular administration when given as supplements The present study was therefore designed and performed to assess the effects of ***Withania somnifera*** (Ashwagandha) and Terminalia arjuna (Arjuna) individually and as a combination on maximum velocity, average absolute and relative Power, balance, maximum oxygen consumption (VO2 max) and blood pressure in humans. Forty normal healthy. Subjects (either sex, mean age 20.6 ± 2.5yrs and mean Body Mass Index 21.9 ± 2.2) were recruited after written informed consent was obtained. Institutional Ethics Committee permission was also obtained. Thirty participants were assigned to experimental group of which 10 received standardized root extracts of ***Withania somnifera***, 10 received standardized bark extract of Terminalia arjuna and the rest of the 10 received standardized root extract of ***Withania somnifera*** in addition to bark extract of Terminalia arjuna both. Both

the drugs were given in the form of capsules (dosage 500mg/day for both the drugs). Ten participants received placebo (capsules filled with flour). All the subjects continued the regimen for 8 weeks. All variables were assessed before and after the course of drug administration. This study showed that ***Withania somnifera*** increased velocity, power and VO2 max whereas *Terminalia arjuna* increased VO2 max and lowered resting systolic blood pressure. When given in combination, the improvement was seen in all parameters except balance and diastolic blood pressure. ***Withania somnifera*** may therefore be useful for generalized weakness and to improve speed and lower limb muscular strength and neuro-muscular co-ordination. *Terminalia arjuna* may prove useful to improve cardio-vascular endurance and lowering systolic blood pressure. Both drugs appear to be safe for young adults when given for mentioned dosage and duration.

234. Sarokte, A. S. and M. V. Rao (2013). "**Effects of Medhya Rasayana and Yogic practices in improvement of short-term memory among school-going children.**" AYU **34**(4): 383–389.

Excellent memory, extraordinary intelligence, great academic achievement, and successful career are the dreams of every individual in this era of competition and professionalism. A good memory power acts as a catalyst in all walks of life, be it academic success or maintenance of personal relationships. It is observed that an average man uses only 10% of his natural memory. Remaining 90% is left unused in a haphazard manner. As per the American psychologist Carl Emil Seashore, if one is alert and makes systematic attempts to awaken and use the natural memory properly, his/her natural memory would be activated creatively and would offer benefits of higher order. A comparative study was conducted comprising 90 subjects to know the efficacy of Medhya Rasayana and Yogic practices in short-term memory of school-going children. The study was conducted over a period of 3 months. It was an open, prospective, and randomized clinical study. The subjects of group A formed the control group and they were observed silently for 3 months without any intervention. The subjects in group B were administered with Choorna (powder) of four Medhya Rasayanas, Mandukaparni (*Centella asiatica* Linn.), Yashtimadhu (*Glycyrrhiza glabra* Linn.), Guduchi [***Tinospora cordifolia*** (Willd.) Miers ex Hook. f. and Thoms.], and Sankhapushpi (*Convolvulus pluricaulis* Choisy), at a dose of 2 g twice daily with milk. Subjects belonging to group C were advocated regular Yogic practices of Asanas, Pranayama, and Dhyana. Further study revealed that among the three groups, group B treated with Medhya Rasayana showed highly significant and most effective changes with respect to objective parameters in the tests, i.e. (1) short-term memory test pictures and (2) serial recall effects test using memory scope. Among the three groups, group C treated with Yogic practices showed highly significant and most effective changes with respect to subjective and objective parameters in mini mental status scale i.e. test 3. The treatment is cost effective and devoid of side effects, which can be beneficial for the community. Mean increase after first follow-up in group B was higher as compared to group C. This shows that Medhya Rasayanas are quick in action and bring about improvement in memory faster when compared with Yogic practices. So, on the whole, group B can be considered to be the most efficient among the three groups.

235. Sarris, J., A. Panossian, I. Schweitzer, C. Stough and A. Scholey (2011). "**Herbal medicine for depression, anxiety and insomnia: A review of psychopharmacology and clinical evidence.**" European Neuropsychopharmacology **21**(12): 841-860.

Research in the area of herbal psychopharmacology has increased markedly over the past decades. To date however, a comprehensive review of herbal antidepressant, anxiolytic and hypnotic psychopharmacology and applications in depression, anxiety and insomnia has been absent. A search of MEDLINE (PubMed), CINAHL, PsycINFO, and the Cochrane Library databases was conducted (up to February 21st 2011) on commonly used psychotropic herbal medicines. A review of the literature was conducted to ascertain mechanisms of action of these botanicals, in addition to a systematic review of controlled clinical trials for treatment of mood, anxiety and sleep disorders, which are common comorbid psychiatric disorders. Specific emphasis was given to emerging phytomedicines. Analysis of evidence levels was conducted, as were effect sizes (Cohen's d) where data were available. Results provided evidence of a range of neurochemical, endocrinological, and epigenetic effects for 21 individual phytomedicines, which are detailed in this paper. Sixty six controlled studies were located involving eleven phytomedicines. Several of these provide a high level of evidence, such as Hypericum perforatum for major depression, and Piper methysticum for anxiety disorders. Several human clinical trials provide preliminary positive evidence of antidepressant effects (Echium amoenum, Crocus sativus, and Rhodiola rosea) and anxiolytic activity (Matricaria recutita, Ginkgo biloba, Passiflora incanata, E. amoenum, and Scutellaria lateriflora). Herbal medicines such as ***Withania somnifera*** and *Centella asiatica* may also provide an adaptogenic effect applicable in cases of comorbid fatigue. Caution should however be taken when interpreting the results as many studies have not been replicated.

236. Saxena, A., S. Dixit, S. Aggarwal, V. Seenu, R. Prashad, S. Bhushan, V. Tranikanti, M. Misra and A. Srivastava (2008). "**An ayurvedic herbal compound to reduce toxicity to cancer chemotherapy: a randomized controlled trial.**" Indian Journal of Medical and Paediatric Oncology **29**(2): 11-18.

Maharishi Amrit Kalash (MAK) is an ayurvedic compound containing many herbs rich in antioxidants. Authors evaluated its role in reduction of chemotherapy toxicity among women with breast cancer. Maharishi Amrit Kalash (MAK), MAK-4 and MAK-5 collectively is an herbal formulation derived from the Indian system of medicine known as 'Ayurveda'. This herbal formulation has been used for general betterment of health since antiquity. The MAK- 4 is prepared in a paste form while MAK-5 is dispensed as tablets. The ingredients of MAK-4 are ***Terminalia chebula***, ***Phyllanthus emblica***, *Elettaria cardamomum*, *Cyperus rotundus*, *Curcuma longa*, ***Piper longum***, *Santalum album*, *Cyperus scariosus*, *Mesua ferrea*, *Convolvulus pluricaulis*, *Glycyrrhiza glabra*, *Embelia ribes*, *Centella asiatica*, ghee, honey and sugar. The ingredients of MAK-5 are ***Withania somnifera***, *Glycyrrhiza glabra*, *Ipomoea digitata*, *Asparagus adescendens*, ***Emblica officinalis***, ***Tinospora cordifolia***, *Asparagus racemosus*, *Convolvulus pluricaulis*, *Vitex trifolia*, *Argyreia speciosa*, *Curculigo orchioides*, *Capparis aphylla*, and *Acacia arabica*. Patient and Methods: Authors recruited 214 patients with breast carcinoma receiving cyclophosphamide, methotrexate and 5- flourouracil (CMF) or cyclophosphamide, adriamycine,& 5-flourouracil (CAF), adjuvant or neo-adjuvant chemotherapy. The toxicity of

chemotherapy was assessed according to WHO criteria. Statistical analysis was carried out on Epi-info 6 and STATA-7. All patients received same antiemetic therapy with ondensetron and dexamethasone. Results show that there was a significant reduction in toxicities observed in MAK group throughout chemotherapy cycles: Poor performance status was prevented by concomitant administration of MAK along with chemotherapy. (Prevented Fraction (PF)=60.6% (95% confidence interval 22.1 to 80.1 ; p value =0.005). Vomiting was prevented by MAK {PF=40.3%, (95% confidence interval 15.1 to 58.1; p value=0.002)}. Similarly anorexia was reduced with PF= 35.6%. (95% confidence interval 17.6 to 49.7, p value = 0.0001) in MAK group. No improvement occurred in stomatitis, diarrhea, alopecia and leucopenia. No overgrowth of tumours occurred in the group treated with Neoadjuvant chemotherapy receiving MAK. Conclusion is that MAK may be used as a supplement along with chemotherapeutic drugs for reducing chemotherapy induced vomiting, anorexia and improving general well being of patients.

237. Seely, D. and R. Singh (2007). "**Adaptogenic potential of a polyherbal natural health product: Report on a longitudinal clinical trial.**" Evidence-based Complementary and Alternative Medicine **4**(3): 375-380.

Stress is a risk factor for a number of diseases and is an important predictor of health in general. Herbal medicines have been used as adaptogens to regulate and improve the stress response and there is evidence to support the use of herbal medicines for this purpose. Authors conducted an open-label longitudinal study on the natural health product, OCTA©, a compound mixture of eight herbs (***Withania somnifera***, *Lagerstroemia speciosa*, *Bacopa monniera*, *Zizyphus jujuba*, *Morinda citrifolia*, *Punica granatum*, *Shisandrae chinensis* and *Lycium barbarum*), to determine its effects on perceptions of stress. Eighteen participants were enrolled in the study and were followed over a period of 3 months. Primary endpoints included scores from four validated questionnaires (SF-36v2, PSS, STAI and BDI-II), serum DHEA, ALT, AST and creatinine all measured at 12 weeks. Seventeen patients completed the study. Except for the physical summary score of the SF36 questionnaire, all the subjective scores indicated a highly significant (P < 0.0001) improvement in the participants' ability to cope with stress. No adverse effects were reported and there was no evidence of damage to the liver or kidney based on serum markers. Initial evidence for this polyherbal compound supports its potential as an effective 'adaptogenic' aid in dealing with stress. Further research using a randomized controlled design is necessary to confirm the findings from this pilot study.

238. Shailaja, U., N. Rao Prasanna, G. R. Arun Raj and V. Mallannavar (2013). "**Effect of Kumarabharana rasa on chronic tonsillitis in children: A pilot clinical study.**" International Journal of Research in Ayurveda and Pharmacy **4**(2): 153-157.

Objective of the study was to assess the effect of Kumarabharana Rasa in the management of chronic tonsillitis (Tundikeri) in children. This study was pilot clinical study with single arm with pre and post test design at outpatient level in a tertiary Ayurveda hospital attached to teaching institute located in district headquarters in Southern India. 16 patients of chronic tonsillitis satisfying diagnostic criteria and age 5-10 years were selected from outpatient department of Kaumarbhritya, Shri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan. Patients

were treated with Kumarabharana rasa (tablet form) in the dose of 500mg once daily for 30 days. The percentage of relief in various assessment criteria were observed which are Kathina shotha (enlargement of tonsils) (43.20%), Ragatwa (hyperemia) (48.83%), Galoparodha (dysphagia) (47.48%), Mukha daurgandhya (halitosis) (49.68%), Lasikagranthi vriddhi (enlargement of lymph nodes) (37.72%) and Jwara (improvement in fever) (85.71%). Kumarabharana Rasa is effective in reducing the signs and symptoms of chronic tonsillitis. Various constituents of drug include *Acorus calamus* extract; *Bacopa monnieri* extract; calcium oxide; ***Emblica officinalis*** extract; ginger extract (***Zingiber officinale***); *Glycyrrhiza glabra* extract; gold; kumarabharana rasa; natural product; *Ocimum tenuiflorum* extract; ***Piper longum*** extract; plant extract; respiratory tract agent; silver; ***Terminalia chebula*** extract; ***Tinospora cordifolia*** extract; ***Withania somnifera*** extract.

239. Shailaja, U., P. N. Rao, P. Debnath and A. Adhikari (2014). "**Exploratory study on the ayurvedic therapeutic management of cerebral palsy in children at a tertiary care hospital of Karnataka, India.**" Journal of Traditional and Complementary Medicine **4**(1): 49-55.

Cerebral palsy (CP) is the leading cause of childhood disability affecting cognitive function and developments in approximately 1.5 to 3 cases per 1000 live births. Based on Ayurvedic therapeutic principles, CP patients were subjected to Abhyanga (massage) with Moorchita Tila Taila (processed sesame oil) and Svedana (fomentation) with Shastikashali Pinda Sveda (fomentation with bolus of drugs prepared with boiled rice). Study group received Mustadi Rajayapana Basti (enema with herbal decoction) and Baladi Yoga (a poly-herbo-mineral formulation), while the placebo group received Godhuma Vati (tablet prepared with wheat powder) and saline water as enema. Treatment with Mustadi Rajayapana Basti and Baladi Yoga improved the activities of daily life by 8.79%, gross motor functions by 19.76%, and fine motor functions 15.05%, and mental functions like memory retention got improved by 15.43%. The placebo group showed an improvement of 0.21% in daily life activities, 2.8% in gross motor, and 2.4% in fine motor functions. Mustadi Rajayapana Basti and Baladi Yoga proved to be more supportive in improving the motor activities and gross behavioral pattern. Further clinical trials are required to evaluate and validate the maximum effect of the combination therapy in a large sample with repetition of the courses for longer duration. Study drugs were as follows: 1. Mustadi Rajayapana Basti: Musta (Cyperus rotundas Linn.), Usheera [Vetiveria zizanioides (Linn.) Nash], Patha (Cissampelos pareira Linn.), Amrita [***Tinospora cordifolia*** (Thunb.) Miers], Tikta (Picrorhiza kurroa Royle ex Benth), Aragwadha (Cassia fistula Linn.), Bala (Sida cordifolia Linn.), Rasna (Alpinia officinarum Hance), Punarnava (Boerhavia diffusa Linn.), Manjistha (Rubia cordifolia Linn. sensu Hook. f.), Brihati (Solanum indicum Linn.), Gokshura (Tribulus terrestris Linn.), Shalaparni [Desmodium gangeticum (Linn.) DC.], Prisniparni [Uraria picta (Jacq.) DC.], Kantakari (Solanum xanthocarpum Schrad. and Wendl.), Madanaphala [Randia dumetorum (Retz.) Poiret], Trayaman (Gentiana kurroo Royle), Satapuspa (Anethum sowa Kurz.), Yastimadhu (Glycyrrhiza glabra Linn.), Priyangu (Callicarpa macrophylla Vahl.), Kutaja (Holarrhena antidysenterica Wall.), Daruharidra (Berberis aristata DC.), Saidhava Lavana (Himalayan pink rock salt), Madhu (honey), Ghrita (butter oil), Ksheera (cow's milk), Mamsa rasa (goat meat soup). 2.Baladi Yoga: Bala (Sida

cordifolia Linn.), Prasarani (Paederia foetida Linn.), Eranda Mula (Ricinus communis Linn.), Ashwagandha (***Withania somnifera*** Dunal), Lashuna (Allium sativum L.), Kumari [Aloe vera (L.) Burm. f.], Mandukaparni [Centella asiatica (Linn.) Urban], Shuddha Rasaka [purified zinc carbonate (ZnCO3)], Shuddha Mandura [purified iron silicate (Fe2SiO4)], Abhraka Bhasma [purified powdered talc, Biotite Calx]. 3.Godhuma Vati (placebo): Wheat powder processed and prepared in tablet form. 4.Sterilized saline water (placebo).

240. Sharma, D. N. and A. Sharma (2015). "***Tinospora cordifolia*** **enhances vyadhikshamatwa (immunity) in children.**" The Journal of Phytopharmacology **4**(4): 227-230.

The immune system in children is constantly developing and they are at an increased risk of infections. It is vital to help enhance immunity by vaccination but more people are turning towards traditional medicines today. The vast flora of the world offers newer options to this effect and is worth exploring. ***Tinospora cordifolia*** (Guduchi) is one such plant which has been traditionally used for various health conditions and is also proven to be an immunomodulator. Objective was to evaluate the role of ***Tinospora cordifolia*** in status of Vyadhikshamatwa (immunity) in children. It was an open-labelled, placebo-controlled, randomized controlled trial conducted in 400 children aged 1-15 years, with 200 each in control and test groups. Study drug and placebo were administered orally at a dose of 100 mg/kg body weight twice daily with honey for 2 months. Response was assessed by total leucocyte count (TLC), lymphocyte percentage and absolute lymphocyte count (ALC). Results were analysed statistically using repeated measures Analysis of Variance (ANOVA) for intra-group comparisons and unpaired t-test for intergroup comparisons using Statistical Packages for Social Sciences (SPSS) software version 20.0. The test drug showed statistically significant increase in TLC ($P<0.001$), ALC ($P<0.001$) and lymphocyte percentage ($P<0.001$) as compared to placebo. Also the rate of infections in the trial group were significantly lesser during the study period ($P<0.001$). In conclusion, ***Tinospora cordifolia*** significantly improves immunity in children and can be used as an adjuvant to vaccination.

241. Sharma, K. (2013). "**A clinical study of Guduchi *Tinospora cordifolia* Willd Miers ex Hook f Thoms in antihyperlipidemic effect wsr to sthaulya.**" International Journal of Pharmaceutical & Biological Archive **4**(3): 472 - 475.

A science is that which contributes to faith and this faith further gives scope to science. Such a science is Ayurveda, which is intended to be in the shadow of faith and in the service of its highest ideals. Ayurveda 'The Vedic System' believes— each plant has a medicinal value that can be utilized as a medicine for particular ailments. Modern Botanist has studied Guduchi as ***Tinospora cordifolia*** (family-menispermaceae). They have mentioned Guduchi as a tonic & also stated its Anti-hyperlipidemic and Anti-hyperglycaemic effect. In present era, Sthoolta is the burning problem which is the by-product of urbanization. It has significant life ruining effect on the patient's quality of life. Not only is this it the root cause of major ailments like Diabetes, Heart Problems, Hypertension, Breathing ailments etc. Thus, according to above discussion, it has become need of the hour to tackle this disease in all direction with the knowledge of different system of medicine prevailing globally. As Ayurveda

the ancient system of medicine has a lot to offer in this direction, therefore an Ayurvedic medicinal plant Guduchi, which brings doshas from Visam state to Sam state, has been choosen to assess its efficacy on Sthaulya Roga (Obesity). Among 30 patients, there are two groups A & B of 15 patients each, in which all subjective as well as objective parameters were analyzed. In this study authors found that Guduchi Kwatha is more effective than Guduchi Sattva because active constituents of the drug are more in Kwatha form and also Kwatha gets absorbed more easily and quickly than the Sattva which has large amount of starch in it.

242. Sharma, L. and I. Sharma (2009). "**A comparative drug trial on Santarpanottha Madhumeha Vishesha (Syndrome X).**" AYU **30**(1): 22-28.

Syndrome-X has emerged as an area of special interest to medical faculty as it houses worst lifestyle pathologies in one patient. There being unknown common ground to Diabetes Mellitus, Hypertension, Obesity & dyslipidemia, the nomenclature adopted is Syndrome-X. As these diseases are observed to be led by Diabetes Mellitus, the other names of the syndrome are Metabolic Syndrome & Insulin resistant syndrome. This is why the Ayurvedic name attributed is 'Santarpanottha Madhumeha Vishesha'. The present study was aimed at observing & evaluating the common Nidana along with a comparative clinical study of two herbo-mineral compounds. 100 diagnosed patients of Syndrome-X were selected and randomly divided in two groups of fifty patients each; Group-A receiving Compound - A, Whereas Group-B receiving Compound - A with Medohara (Navak) Guggulu respectively. The vehicle for both the groups was Dashamoola decoction in a dose of 40 ml twice a day for 45 days. It was observed that most patients in group -B had significant improvement in Shrama, Prabhoot mootrata, Daurbalya, Vibandha, Kanthatalu shosha, Pipasadhikya & Sada. Compound A contained ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) among other drugs, and Medohara (Navak) Guggulu contained ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***), ***Trikatu*** (***Zingiber officinale, Piper longum, Piper nigrum***), *Trimada* & Guggulu.

243. Sharma, M. R., C. S. Mehta, D. J. Shukla, K. B. Patel, M. V. Patel and S. N. Gupta (2013). "**Multimodal Ayurvedic management for Sandhigatavata (Osteoarthritis of knee joints).**" AYU **34**(1): 49-55.

Vata is the governing factor in the maintenance of equilibrium in the universe as well as in the body. As age advances, the influence of Vata Dosha progresses, resulting in the process of gradual degeneration of the body. Sandhigatavata (osteoarthritis) is one of the consequences of this process, which is common in the elderly people. This is one of the major causes of chronic disability, affecting the quality of life. Prevalence of osteoarthritis in India is more among menopausal women. This study has been conducted to evaluate the efficacy of Ayurvedic multimodal management in Sandhigatavata and to provide better options to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). In present clinical trial, 50 patients of Sandhigatavata have been registered and have been given Snehana, Svedana, Mriduvirechana, Matrabasti, and Jalaukavacharana, along with oral medications like Yogaraja Guggulu and Ashvagandha Churna. Yogaraja Guggulu contains many herbs including ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) and ***Trikatu Zingiber officinale, Piper longum, Piper nigrum***). Ashvagandha Churna (root

powder of *Withania somnnifera* Dunal.) 3 g with warm milk was given in morning and evening before meals. This multimodal therapy is being used in P.D. Patel Ayurved Hospital, Nadiad, since years, providing good relief to patients with Sandhigatavata. The results have been analyzed statistically by using the Student paired't' test. The therapy showed highly significant ($P < 0.001$) beneficial effect on the clinical features of Sandhigatavata. On overall effect of therapy, 4% of the patients were relieved completely, while 24% have shown marked improvement, 50% moderate improvement, and 22% mild improvement. Results of follow-up showed that marked improvement decreased, but moderate improvement was steady. Continuing the study on a larger number of patients, with inclusion of more objective parameters to get better conclusions is suggested at the end of the study.

244. Sharma, R., H. Amin, G. Ruknuddin and P. K. Prajapati (2015). "**Efficacy of Ayurvedic remedies in type 2 diabetes: A review through works done at Gujarat Ayurved University, Jamnagar.**" Journal of Medical Nutrition and Nutraceuticals **4**(2): 63-69.

Prevalence of diabetes mellitus (DM) is rapidly rising throughout the globe at an alarming rate, where India leads with largest number of diabetics and became "diabetes capital of the world." Currently available conventional options for diabetes have certain limitations; considering which options from alternative resources are being searched to meet the need. Ayurveda, the traditional system of Indian subcontinent hold huge number of remedies that can be useful in the treatment of diabetes and associated complications. To revalidate the actual efficacy of these formulations in DM (~Madhumeha); many studies have been carried out at different research centers of India. The current attempt is aimed to compile such works done at two Post Graduate institutes of Gujarat Ayurved University during 2000-2013. These studies aimed at establishing the impact of various Ayurvedic treatment modalities viz. Shodhana (purification/cleansing procedures) and Shamana (pacifying medicinal treatment) etc., in DM. These therapies were found to increase quality of life, significantly effective and clinically safe as no adverse drug reactions were reported during the treatment period. Citing a clinical trial (in the form of a thesis) the paper reports that *Guduchi Ghana*, i.e., ***Tinospora cordifolia***, has mild hypoglycaemic and significant antihyperglycaemic activity, while Guduchi Satva showed mild hypoglycaemic and insignificant antihyperglycaemic activities. Both drugs administered at a dose of 500 mg twice daily 30 min before meal for 28 days provided encouraging results (Clinical Trials Registry India [CTRI]/2012/01/002368). Highly significant relief ($P < 0.001$) in all signs and symptoms were reported in both the treated groups. In FBS and PPBS, statistically significant reduction ($P < 0.01$) was found in Guduchi Ghana in comparison to Satva (Sharma R. *The Effect of Two Different Dosage Forms of Guduchi, i.e. Satva and Ghana W.S.R Antihyperglycemic Effect on Madhumeha (NIDDM)*. PG Dissertation, Department of Rasa Shastra and Bhaishajya Kalpana, IPGT and RA, Gujarat Ayurved University, Jamnagar; 2012). The paper also notes that the comparative clinical efficacy of Vamana (therapeutic emesis) and Virechana was also studied. 1 g of Guduchi Satva (starchy extract of ***Tinospora cordifolia*** [Willd.] Miers) twice daily for 28 days was administered after Vamana and Virechana in two different groups. HbA1c was reduced by 8.3% after Vamana, while it was 3.5% after Virechana. FBS and postprandial blood sugar (PPBS) were also responded more with Vamana than Virechana (Pandey R. *A Comparative Clinical*

Study of Vamana and Virechana Karma in the Management of Sthula Pramehi W.S.R to Type II Diabetes mellitus. PG Dissertation, Department of Panchakarma, IPGT and RA, Gujarat Ayurved University, Jamnagar; 2010).

245. Sharma, R. K. and P. S. Patki (2010). "**Double-blind, placebo-controlled clinical evaluation of an Ayurvedic formulation (GlucoCare capsules) in non-insulin dependent diabetes mellitus.**" Journal of Ayurveda and Integrative Medicine **1**(1): 45-51.

Diabetes mellitus describes a metabolic disorder of multiple etiologies characterized by insulin resistance, relative insulin deficiency and hyperglycemia with disturbances of carbohydrate, fat and protein metabolism. The goal for treatment of diabetes is to prevent its acute manifestations and long-term microvascular and macrovascular complications. The present study was conducted to evaluate the efficacy and safety of an Ayurvedic formulation (GlucoCare Capsules) in non-insulin dependent diabetes mellitus. Fifty NIDDM patients of pitta-kapha prakriti attending the outpatient department of the Government Ayurvedic Medical College, Guwahati, Assam, India were included in the study, and randomly divided into 2 groups, GlucoCare and placebo. The drug contains ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***), ***Trikatu Zingiber officinale, Piper longum, Piper nigrum***) and ***Tinospora cordifolia*** among others. All received either GlucoCare or placebo in a dose of 2 capsules twice daily, before meals for 3 months. All 50 patients completed the study-no drop outs, withdrawals or patients lost to follow up. The GlucoCare group showed significant improvement in symptoms from the 2nd month till the end of the study. GlucoCare was well tolerated by all patients throughout the treatment period with no evidence of adverse effects. The study indicates clinical efficacy of GlucoCare Capsules in the management of NIDDM in those belonging to pitta-kapha prakriti. The formulation is well tolerated and appears safe in the dosage used.

246. Sharma, V. and A. K. Chaudhary (2015). "**Pharmaceutical standardization of a novel anti leukemic Ayurvedic herbomineral formulation.**" International Journal of Pharmaceutical & Biological Archive **6**(1): 49 - 58.

The aim of this pharmaceutical study was to develop standard manufacturing process of Leukchem 14, a novel herbo-mineral formulation, which was designed for the treatment of Leukemia. The drug consists in specific proportions of dried powders of Ashwagandha (***Withania somnifera*** Dunal.) root, Bilwa (*Aegle marmelos* Carr.) fruit pulp, Guduchi (***Tinospora cordifolia*** (Willd) Miers.) stem, Haridra (*Curcuma longa* Linn.) rhizome, Kanchanar (*Bauhinia variegata* Blume) stem bark and ***Triphala*** (***Terminalia bellirica***, ***Terminalia chebula***, ***Emblica officinalis***), and mineral drugs viz. Samaguna Kajjali (black sulphide of purified Mercury) and Shuddha Manahshila (purified Realgar). By adopting the principles of Kharaliya Rasayana, the homogenous mixture was prepared with these drugs, which was further levigated with fresh cow urine and decoction of Manjishtha (*Rubia cordifolia* Linn.) root respectively each three times in three batches. During the procedures of Shodhana and Bhavana, there were various physicochemical changes were observed. In first step, 317.82, 319.25, and 318.0 g of weight with the Bhavana of Gomutra was obtained from 306.50 g of basic homogenous mixture of herbal Churna, Kajjali and Shuddha Manahshila in I, II, and III batches respectively. In second step, 244.79, 241.72, and 243.00 g of Leukchem 14 with the Bhavana of Manjishtha Kwatha was obtained from 200 g of Gomutra Bhavita

materials in I, II, and III batches respectively. The percentage increase in weight was observed after levigation with both the media progressively, 3.87 % by cow urine and 21.59% by Manjishtha Kwatha. At the end of Pharmaceutical study, dark brown coffee coloured powder was obtained.

247. Shawkat, H., M. Yakoot, T. Shawkat and S. Helmy (2015). "**Efficacy and safety of a herbal mixture (Viron® tablets) in the treatment of patients with chronic hepatitis C virus infection: a prospective, randomized, open-label, proof-of-concept study.**" Drug Design, Development and Therapy **9**: 799–804.

Development of an optimal interferon-free regimen for chronic hepatitis C virus infection is believed to require the combination of different drug classes to provide good antiviral efficacy, clinical and quality of life benefits, as well as a high barrier to resistance. Viron® is a new herbal drug in film-coated tablet form, and is based on a mixture of herbs with known hepatoprotective and antiviral properties. Authors conducted this study to explore the safety and the potential clinical and quality of life benefits of this product in patients with chronic hepatitis C infection. Viron® is a herbal drug manufactured by European Egyptian Pharmaceutical Industries (Alexandria, Egypt) as a film-coated tablet formulation. It is a mixture of herbs with known hepatoprotective and antiviral properties. Each 1 g film-coated tablet contains dried powdered ***Tinospora cordifolia*** (whole plant) 200 mg, *Glycyrrhiza glabra* (root) 100 mg, *Elettaria cardamomum* (seeds) 200 mg, *Curcuma longa* (rhizome) 200 mg, *E. alba* (whole plant) 200 mg, and *Rumex crispus* (whole plant) 100 mg. Eighty-two consecutive patients presenting to outpatient clinics as already-known or newly-diagnosed cases of chronic hepatitis C virus (HCV) infection, were entered into the study and randomized to three groups to receive escalating doses of Viron for 6 months. Virological, clinical, and enzyme responses, as well as quality of life index scores for chronic liver disease were compared between the groups. Of the 20 patients treated with the highest dose of Viron (three tablets twice daily), two (10%) had a complete virological response at the end of treatment (ETR) and two (10%) had a partial ETR, defined as a decrease in viral load of at least 2-log10 at the end of 6 months of treatment, whereas patients treated with the medium dose (two tablets twice daily) and the lowest dose (one tablet twice daily) showed a significantly lower ETR (P=0.043). Alanine aminotransferase levels and scores on the Chronic Liver Disease Questionnaire improved to a significantly greater extent in the highest dose group (P=0.007 and P=0.021, respectively). No serious adverse effects attributable to the herbal formulation were reported in any of the groups, apart from mild transient nausea, bloating, giddiness, and headache in two patients in the group receiving two tablets twice daily and in three patients in the group receiving three tablets twice daily. It is concluded that this herbal formulation is potentially safe and may offer some added clinical and quality of life benefits when used in the treatment of patients with chronic hepatitis C virus infection. Larger studies could be warranted to evaluate the effects of using this formulation as an add-on therapy to an all-oral combination of a directly acting antiviral drug protocol in the treatment of chronic hepatitis C.

248. Shenoy, S., U. Chaskar, J. S. Sandhu and M. M. Paadhi (2012). "**Effects of eight-week supplementation of Ashwagandha on cardiorespiratory endurance in elite Indian cyclists.**" Journal of Ayurveda and Integrative Medicine **3**(4): 209-214.

Cycling is an endurance sport relying mainly on aerobic capacity to provide fuel during long-duration cycling events. Athletes are constantly searching for new methods to improve this capacity through various nutritional and ergogenic aids. Purpose: The aim of the study was to find out the effect of Ashwagandha on the cardiorespiratory endurance capacity, that is, aerobic capacity of elite Indian cyclists. Materials and Methods: Forty elite (elite here refers to the participation of the athlete in at least state-level events) Indian cyclists were chosen randomly and were equally divided into experimental and placebo groups. The experimental group received 500 mg capsules of aqueous roots of Ashwagandha twice daily for eight weeks, whereas the placebo group received starch capsules. Outcome Measures: The baseline treadmill test for the cyclists were performed to measure their aerobic capacity in terms of maximal aerobic capacity (VO 2 max), metabolic equivalent, respiratory exchange ratio (RER), and total time for the athlete to reach his exhaustion stage. After eight weeks of supplementation, the treadmill test was again performed and results were obtained. Results: There was significant improvement in the experimental group in all parameters, whereas the placebo group did not show any change with respect to their baseline parameters. There was significant improvement in the experimental group in all parameters, namely, VO 2 max (t = 5.356; P < 0.001), METS (t = 4.483; P < 0.001), and time for exhaustion on treadmill (t = 4.813; P < 0.001) in comparison to the placebo group which did not show any change with respect to their baseline parameters. Conclusion: Ashwagandha (*Withania* spmnifera) improved the cardiorespiratory endurance of the elite athletes.

249. Shidfar, F., A. Rajab, T. Rahideh, N. Khandouzi, S. Hosseini and S. Shidfar (2015). "**The effect of ginger (*Zingiber officinale*) on glycemic markers in patients with type 2 diabetes.**" Journal of Complementary and Integrative Medicine **12**(2): 165-170.

Ginger (***Zingiber officinale***) is one of the functional foods which contains biological compounds including gingerol, shogaol, paradol and zingerone. Ginger has been proposed to have anti-cancer, anti-thrombotic, anti-inflammatory, anti-arthritic, hypolipidemic and analgesic properties. Here, authors report the effect of ginger supplementation on glycemic indices in Iranian patients with type 2 diabetes. Methods: A double-blind, placebo-controlled, randomized clinical trial was conducted on 20-60 -year-old patients with type 2 diabetes who did not receive insulin. Participants in the intervention and control groups were received 3 g of powdered ginger or placebo (lactose) (in capsules) daily for 3 months. Glycemic indices, total antioxidant capacity (TAC), malondialdehyde (MDA), C-reactive protein (CRP), serum paraoxonase, dietary intake and physical activity were measured at the beginning and end of the study, and after 12 h fasting. Results: Comparison of the indices after 3 months showed that the differences between the ginger and placebo groups were statistically significant as follows: serum glucose (-19.41±18.83 vs. 1.63±4.28 mg/dL, p<0.001), HbA<inf>1c</inf> percentage (-0.77±0.88 vs. 0.02±0.16, p<0.001), insulin (-1.46±1.7 vs. 0.09±0.34 μIU/mL, p<0.001), insulin resistance (-16.38±19.2 vs. 0.68±2.7, p<0.001), high-sensitive CRP (-2.78±4.07 vs. 0.2±0.77 mg/L, p<0.001), paraoxonase-1 (PON-1) (22.04±24.53 vs. 1.71±2.72 U/L, p<0.006), TAC (0.78±0.71 vs.

-0.04±0.29 µIU/mL, p<0.01) and MDA (-0.85±1.08 vs. 0.06±0.08 µmol/L, p<0.001) were significantly different. This report shows that the 3 months supplementation of ginger improved glycemic indices, TAC and PON-1 activity in patients with type 2 diabetes.

250. Shivakumar, S., K. Ilango, G. P. Dubey, N. Subhasree and A. Agrawal (2015). "**Evaluation of plant based formulation on adolescent obesity and its associated bio-markers: A randomized, double blind, placebo controlled study.**" Complementary Therapies in Medicine **23**(2): 157-164.

Obesity and overweight are the fifth most fatal diseases leading to an increased rate of morbidity and mortality in global population, with its incidence increasing drastically. Taking this into consideration present study was conducted in order to explore the efficacy of plant based formulation in the management of adolescent obesity and its associated biomarkers. The test formulation was a hydroalcoholic extract of three plants (*Hippophae rhamnoides*, *Dioscorea bulbifera* and ***Terminalia chebula***), and each 500 mg capsule contains *D. bulbifera* (175 mg/kg), *T. chebula* (160 mg/kg) and H. rhamnoides (137 mg/kg) and remaining was additive (calcium carbonate 90% and starch 10%). Both test formulation and placebo capsules were manufactured by Varanasi Bioscience Pvt Ltd, UP, India, and was administered twice a day (BID). The test formulation contained chief biomarkers such as chebulic acid from T. chebula, quercetin and isorhamnetin from H. rhamnoides, and diosgenin from D. bulbifera, etc., which were isolated and quantified for their active concentration in each batch. There was no difference in the odor and appearance of both placebo and test formulation capsules. Randomized, double blind, placebo controlled trial was conducted in 130 obese adolescent of both sexes, with BMI above 25kg/m2. The subjects were randomly assigned into test formulation group (TFG) and placebo group (PG). TFG received two 500mg capsule containing test formulation whereas, the PG received two 500mg of cellulose powder containing capsule daily for 3 months. The parameters such as blood pressure, inflammatory cytokines, adipokines and lipid profile were assessed in all subjects pre and post treatment. There was a considerable improvement in the levels of lipid profile, inflammatory cytokines, adipokines and blood pressure after treatment in TFG compared to PG. The statistical difference obtained between the groups after three months of treatment for the various biomarkers are given as mean with 95% CI for BMI (-1.4 ± 0.6 (-2.5 to -0.7)), total cholesterol mg/dl (-20.9 ± 5.0 (-30.8 to -11.0)), triglyceride mg/dl (-12.9 ± 5.7 (-23.9 to -1.2)), HDL-c mg/dl (7.2 ± 0.8 (5.6-8.8)), IL-6 (-0.7 ± 0.1 (-0.9 to -0.6)), hs C-reactive protein (CRP) mg/l(-1.0 ± 0.01 (-1.2 to -0.8)), adiponectin µg/ml(4.9 ± 0.4 (4.2-5.7)), leptin ng/ml (-8.0 ± 1.4 (-10.7 to -5.3)), diastolic blood pressure (DBP) mmHg (-10.4 ± 0.8 (-12.0 to -8.7)) and systolic blood pressure (SBP) mmHg (-6.7 ± 0.7 (-8.1 to -5.3)). Also, there was a statistical significance within group TFG. The study concludes that the test formulation may prevent the future cardio vascular risk incidence in obese adolescents by reducing inflammation, overweight, lipid profile and by regulating adipokines. Thus it may help to improve the health pattern in obese patients with least side effects.

251. Sinha, R. R., N. Sharma, U. Advani, G. Dadheech, S. Kulshreshtha and R. Parakh (2014). "**Comparative study of hypolipidemic effects of atorvastatin with *Emblica officinalis***

(Amla) in patients of type II hyperlipidemia." World Journal of Pharmaceutical Research **3**(2): 2799-2810.

The present study was undertaken for an evaluation of the effect of ***Emblica officinalis*** powder on the serum lipids level & comparing standard hypolipidemic drug Atorvastatin in the patients of hyperlipidemia type II at NIMS Medical College & Hospital, Jaipur. A prospective randomized open label study was done in medicine O.P.D. NIMS Hospital Jaipur from November 2011 to April 2013 after taking ethical clearance and written informed consent. Out of 93 patients, 45 patients (Group-A) were given two tablet of Amla (500 mg) daily, while the other 48 patients (Group-B) received one tablet of Atorvastatin (10 mg) daily for 16 weeks. All routine biochemical investigations including lipid profile were performed before starting the intervention as well as after completion of each treatment round i.e at the end of 4 weeks, 8 weeks, 12 weeks & 16 weeks. Amla showed significant increase in HDL and decrease in triglyceride level (P0.05) at the end of 16 wks while atorvastatin has shown better effect on TC, LDL and VLDL (P0.05). There was no adverse drug event in either group. In this study on amla when compared with atorvastatin, amla has been shown better effect on TG and HDL while atorvastatin has shown better effect on TC, LDL and VLDL.

252. Singh, B. B., S. P. Vinjamury, C. Der-Martirosian, E. Kubik, L. C. Mishra, N. P. Shepard, V. J. Singh, M. Meier and S. G. Madhu (2007). "**Ayurvedic and collateral herbal treatments for hyperlipidemia: A systematic review of randomized controlled trials and quasi-experimental designs.**" Alternative Therapies in Health and Medicine **13**(4): 22-28.

Ischemic heart disease (IHD) is a leading cause of morbidity and mortality in both developing and developed countries. An underlying cause of IHD involves retention and deposit of serum lipids in coronary arteries, decreasing blood flow. Drugs (conventional and herbal) are used to lower levels of serum cholesterol to help prevent IHD. The Ayurvedic medicine pharmacopoeia identified herbs that might contribute to a decrease in cholesterol and therefore reduce the risk of IHD. Literature searches were conducted at 3 points: 2003, 2004, and 2007. Databases searched included PubMed, the National Library of Medicine, the National Center for Complementary and Alternative Medicine, Ovid, and EBSCO Information Services, and other search strategies also were used. Each article was assessed for quality by 3 people, and discrepancies were resolved by arbitration using a fourth person, who also read and scored each article. Additional assessments of safety using a scale and determination of reported efficacy/effectiveness of the randomized controlled trials (RCTs) and quasi-experimental designs (QEDs) were made. RCTs generally received high quality scores and improved by decade of publication. More than 50% of garlic, more than 80% of guggul, and 100% of Arjuna RCTs reported product effectiveness. Some medicines were with ingredients including ***Terminalia chebula*** and ***Phyllanthus emblica***. Safety scores did not improve by decade. The QEDs received medium and high quality scores, and 93% of them reported effectiveness. The QEDs had a higher mean score for safety reporting than the RCTs. Many studies received high quality scores and noted safety information and reported effectiveness or efficacy in a clear manner. This finding was not consistent with other systematic reviews that have found the highest reported efficacy/effectiveness in studies of poorer quality. Ayurvedic herbs reviewed here should be considered by physicians when trying to manage hyperlipidemia in their patients.

253. Singh, H. and Y. Sharma (2011). "**Clinical evaluation of hepato protective effect of Katuki (*Picrorhiza kurroa* Royale ex Benth). Processed in Guduhci (*Tinospora cordifolia* wild.) Miers in patients receiving lipid lowering drugs (statins).**" Indian Journal of Traditional Knowledge **10**(4): 657-660.

The hypolipidaemic drugs have attracted considerable attention because of their potential to prevent cardiovascular disease by retarding the accelerated atherosclerosis in hyperlipidaemic individuals. Statins are the first choice drugs for primary hyperlipidaemias with raised LDL and total cholesterol levels, with or without raised triglycerides levels, as well as for secondary hypercholesterolemia. Statin therapy is commonly associated with liver damage in terms of elevated aminotransaminases. Simultaneous use of hepatotoxicity reducing formulation is desirable for successful continuation of HMG-CoA reductase inhibitor (statins) over a desired period in hyperlipidaemic patients. So, the present clinical study was planned to evaluate the hepatoprotective effect of Katuki (*Picrorhiza kurroa* Royle ex Benth.) processed in Guduchi [***Tinospora cordifolia*** (Wild.) Miers], on scientific parameters. In the present clinical trial, two groups of patients receiving standardized lipid lowering drug (Atrorvastatin 20 mg, twice daily) have been studied to evaluate the hepatoprotective effect of these drugs. The first group was given 2 gm of Katuki processed in Guduchi, twice daily with statin therapy. The second group was given 500 mg of starch powder filled in capsules, twice daily with statin therapy. The trial was conducted for three months and liver functions test were periodically evaluated to assess the hepatoprotective effect of drugs under trial. At the end of the trial, trial group exhibited its hepatoprotective efficiency over the control.

254. Singh, N., S. Mahajan, S. K. Subramani, D. Yadav, L. Singh and G. Prasad (2015). "***Triphala* improves glucose homeostasis by alleviating atherogenic lipids and oxidative stress in human Type 2 diabetes mellitus.**" International Journal of Ayurvedic Medicine **6**(3): 212-219.

'***Triphala***' constituting equal parts of three medicinal dried plant fruits ***Emblica officinalis*** Gaertn., ***Terminalia chebula*** Retz. and ***Terminalia bellirica*** Gaertn. is an antioxidant rich Ayurvedic formulation. The present study assessed therapeutic as well as protective effects of ***Triphala*** on human subjects with Type 2 diabetes mellitus (T2DM) and Impaired glucose tolerance (IGT). ***Triphala*** at a dose of 5 gms BD was administered to two cohorts viz., IGT, N= 20 and T2DM, N=30 consecutively for a period of 12 months. The therapeutic efficacy was assessed quarterly by monitoring blood glucose and lipid levels; the protective effect by monitoring antioxidants level quarterly and DNA damage annually. Toxicity if any, to liver and kidney due to long term administration was assessed quarterly in both cohorts. Continuous '***Triphala***' therapy for 12 months significantly reduced blood glucose ($p \leq 0.001$) and li-pid levels ($p \leq 0.05$) in both the cohorts. ***Triphala*** resisted oxidative stress generated during the course of hypergly-cemia by significantly increasing the activity of super oxide dismutase and Catalase ($p \leq 0.001$) and the level of re-duced glutathione ($p \leq 0.001$). Protective effect on DNA was accessed through significant reduction in the comet tail length ($p \leq 0.001$). In conclusions, '***Triphala***' ameliorated

not only the oxidative stress but also normalized glucose and lipid homeosta-sis in subjects with impaired glucose and T2DM.

355. Smith, C., C. Crowther, K. Willson, N. Hotham and V. McMillian (2004). "**A randomized controlled trial of ginger to treat nausea and vomiting in pregnancy.**" Obstetrics and Gynecology **103**(4): 639-645.

Objective was to estimate whether the use of ginger (***Zingiber officinale***) to treat nausea or vomiting in pregnancy is equivalent to pyridoxine hydrochloride (vitamin B6). A randomized, controlled equivalence trial involving 291 women less than 16 weeks pregnant was undertaken at a teaching hospital in Australia. Women took 1.05 g of ginger or 75 mg of vitamin B6 daily for 3 weeks. Differences from baseline in nausea and vomiting scores were estimated for both groups at days 7, 14, and 21. Ginger was equivalent to vitamin B6 in reducing nausea (mean difference 0.2, 90% confidence interval [CI] -0.3, 0.8), retching (mean difference 0.3; 90% CI -0.0, 0.6) and vomiting (mean difference 0.5; 90% CI 0.0, 0.9), averaged over time, with no evidence of different effects at the 3 time points. For women looking for relief from their nausea, dry retching, and vomiting, the use of ginger in early pregnancy will reduce their symptoms to an equivalent extent as vitamin B6.

256. Somi, M. H., M. Bagheri and M. Ghojazadeh (2015). "**Efficacy of an Iranian herbal preparation (Lax-Asab) in treating functional constipation: A randomized, placebo-controlled clinical trial.**" Journal of Traditional and Complementary Medicine **5**(3): 153-156.

Functional constipation is a common clinical complaint of patients with unsatisfactory treatment outcome. Authors designed this study to evaluate the efficiency of a traditional herbal preparation (Lax-Asab) in treating chronic constipation. In this double-blind, randomized, placebo-controlled clinical trial, participants with chronic constipation (n = 48) were randomly selected to receive either the Lax-Asab powder (n = 24) or placebo (n = 24) on alternative days for 4 weeks. The Lax-Asab powder contains equal amounts of Cassia angustifolia Vahl. (xiá yè fa¯n xiè yè), *Mentha piperita* L. (hú jia¯o bò hé), ***Zingiber officinale*** Rosc. (she¯ng jia¯ng), *Glycyrrhiza glabra* L. (ga¯n cəo). A total of 40 patients completed the study. Authors determined the severity of constipation based on defecation frequency (per week) and defecation difficulties. Of the total of 48 patients who participated, 40 completed the trial [24 men (60%), mean age, 21.0 ± 4.2 years; 16 women (40%), mean age, 20.1 ± 4.3 years]. The mean of weekly defecation frequency increased in both groups; from 1.8 ± 0.41 to 4.8 ± 1.12 times in patients who received Lax-Asab and from 1.7 ± 0.44 to 2.2 ± 0.61 times in patients who received placebo. A time-treatment interaction showed that this increase was significantly higher in the intervention group. Defecation difficulties improved significantly more in patients who received Lax-Asab than patients who received placebo. There was no statistically significant difference between the two groups with regard to the side effects observed. This study confirms the efficacy and tolerability of an Iranian herbal preparation, Lax-Asab, in treating patients with chronic functional constipation.

257. Srinagesh, J. and K. Pushpanjali (2011). "**Assessment of antibacterial efficacy of *Triphala* against mutans streptococci: a randomised control trial.**" Oral health & preventive dentistry **9**(4): 387-393.

Triphala (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) is an ayurvedic preparation with known antimicrobial action. This study was carried out to assess the antibacterial efficacy of ***Triphala*** against salivary mutans streptococci in comparison with the 'gold standard' chlorhexidine. A double blind randomised control trial was conducted among 57 volunteers who were assessed to be in the high caries risk category. They were randomly allocated into three study groups: 1) 15 ml of 6% ***Triphala*** mouthwash; 2) 15 ml of 0.2% chlorhexidine (active control); 3) no mouthwash (passive control). Mouthwashes were given twice a day for 15 days. Unstimulated saliva samples were collected at baseline and at 15 and 45 days. Mutans streptococci (MS) were cultured on MSB agar and colony counts obtained. The α error was fixed at 5%. ANOVA and post-hoc LSD tests were performed using SPSS version 14. After using mouthwash for 15 days, an 83% and 80% reduction and at 45 days a 67% and 65% reduction in salivary MS colony count was observed in the ***Triphala*** and chlorhexidine groups, respectively (P = 0.0001). The control group showed an increase of 3% in MS colony count at 15 days and a reduction of 7% at 45 days. (P = 0.116). The antimicrobial action of ***Triphala*** against mutans streptococci closely parallels that of chlorhexidine. It does not have the side effects commonly associated with chlorhexidine and is cost effective.

258. Sripramote, M. and N. Lekhyananda (2003). "**A randomized comparison of ginger and vitamin B6 in the treatment of nausea and vomiting of pregnancy.**" Journal of the Medical Association of Thailand **86**(9): 846-853.

Objective was to compare the efficacy of ginger (***Zingiber officinale***) to vitamin B6 in the treatment of nausea and vomiting of pregnancy. Study design was taken as a randomized double-blind controlled trial in the Department of Obstetrics and Gynecology, Bangkok Metropolitan Administration Medical College and Vajira Hospital. Subjects were women with nausea and vomiting of pregnancy at or before 16 weeks of gestation, who attended the antenatal care clinic. The subjects requested anti-emetics, had no medical complications, non-hospitalized and were able to attend a one week follow-up visit. From November, 1999 to November 2000, 138 women participated and gave consent for the study. The subjects were randomly allocated into two groups to take either 500 mg of ginger orally or an identical 10 mg of vitamin B6 one capsule three times daily for three days. Subjects graded the severity of their nausea using visual analogue scales before treatment and recorded the number of vomiting episodes in the previous 24 hours and again during three consecutive days of treatment. Main outcome measures were considered as the change of nausea scores and the number of vomiting episodes during three days of treatment. The 64 subjects in each group remained in the study. The demographic data were comparable in both groups. The ginger and vitamin B6 significantly reduced the nausea scores from 5.0 (SD, 1.99) to 3.6 (SD, 2.48) and 5.3 (SD, 2.08) to 3.3 (SD, 2.07) respectively, with $p < 0.001$. The mean score change after treatment with ginger was 1.4 (2.21), less than with vitamin B6, which was 2.0 (2.19) but with no statistically significant difference (95% CI -1.4 to 0.2, p = 0.136). The ginger and vitamin B6 also significantly reduced the number of vomiting episodes from 1.9 (2.06) to 1.2 (1.75) and 1.7 (1.81) to 1.2 (1.50) respectively, with $p < 0.01$. The mean number change after treatment with ginger was 0.7 (2.18), more than with vitamin B6, which was 0.5 (1.44) but with no statistically significant difference, (p = 0.498). There were

some minor side effects in both groups such as sedation (26.6% vs 32.8%, p = 0.439), and heartburn (9.4% vs 6.3%, p = 0.510), a non-significant difference. The nausea score and the number of vomiting episodes were significantly reduced following ginger and vitamin B6 therapy. Comparing the efficacy, there was no significant difference between ginger and vitamin B6 for the treatment of nausea and vomiting during pregnancy.

259. Srivastava, A. K. (2015). "**Role of Amrita Guggulu in the management of Vata-rakta - A Clinical Trial**" International Journal of Pharmaceutical & Biological Archive **5**(4): 45 - 51.

In the present revolutionary era the life of a person is hectic and materialistic. For the survival of fitness, the men expected to remain healthy physically as well as mentally. It is quite difficult due to the various obstacles which are experienced by men during his routine life. The disease Vata-rakta is one of them. It is a burning problem of present era. It has attracted the attention of world's scientists working on the problem, not due to its fatality but due to its remote complications and sequels. If the chronic condition is not treated properly the deformity of joints and cartilages cripples a person throughout his life. Vata-rakta is an ailment where both Vata and Rakta are responsible to lead a complex effect on the joint and produces Vata-rakta. Vata-rakta is a disease of joints and its clinical onset is from great toe which later spreads over other joints of the body. In Chakradutta, Vatavyadhi Rogaadhikaar, Chapter 23, Amrita Guggulu is described. Amrita Guggulu Pratham described therein is taken here for the treatment of Vatarakta. The drug consists mainly of ingredients like Guggulu (*Commiphora mukul*), ***Triphala*** (***Terminalia chebula*** Retz, ***Terminalia bellirica***, ***Emblica officinalis***), Guduchi (***Tinospora cordifolia***). This is a single-blind clinical study with a pre-test and post-test design, wherein a minimum of 30 patients of both sex, suffering from Vata-rakta, in an age limit of 20 to 60 years, were selected randomly and given Amrita Guggulu with an Anupaana of Amritaadi Kashaya72 ml with each dose. The therapeutic effect of the treatment was assessed based on specific subjective and objective parameters. Statistically significant improvement was observed in all the criterion of assessment. The use of Amrita Guggulu as Shamana Aushadha was a perfect selection in the management of Vata-rakta. As a preliminary study, it has paved the further scope of study with bigger sample size in management of Vata-rakta.

260. Sud, K. S. and A. B. Thaker (2013). "**A randomized double blind placebo controlled study of ashwagandha on generalized anxiety disorder.**" International Ayurvedic Medical Journal **1**(5): 1-7.

Generalized Anxiety Disorder (GAD) is the most frequent anxiety disorder which comes across in the primary care settings. Pharmaceutical treatments for GAD are usually associated with various side effects hence herbs like Ashwagandha (***Withania somnifera***) can be used in managing this condition due to its anti-stress and anxiolytic activity. Considering all these points the present placebo controlled study was planned to assess the clinical efficacy of Ashwagandha (***Withania somnifera***) granules in the management of Generalized Anxiety Disorder. In Hamilton's Anxiety Rating Scale insignificant difference was found in both the groups except Anxious mood which showed a highly significant difference (P<0.001). On the whole despite having insignificant statistical difference in both the groups, Group A, Ashwagandha

(***Withania somnifera***) granules showed a better percentage improvement than Group B (Placebo).

261. Sujata, N., S. Kumar, G. D. Gupta and N. Rai (2008). "**Hepato-protective effect of *Triphala* in infective hepatitis (Hepatitis B): A clinical and an experimental study.**" AYU (An international quarterly journal of research in Ayurveda) **29**(3): 176.

Liver is the hub of wheel of life. Liver is one of the extensively explored areas in Modern Medicine. Among the various diseases affecting it, Hepatitis-B virus infection is the most common cause. The clinical symptoms of Hepatitis-B are similar with those described under Kamala Roga in Ayurveda. Hepatitis-B, because of its potential to cause life-threatening complications like Cirrhosis, Ascites, and Hepatocellular Carcinoma, has been kept on the top of National Agenda in Public Health Administration. Hepatitis-B virus infects more than 2 billion people worldwide, out of which 360 millions are chronic carriers annually1 . It is the 10th leading cause of mortality and Hepatocellular Carcinoma is the 5th most common cancer in the world which accounts for 1.2 millions deaths globally every year2 . Western Medicine, despite its enormous success does not offer any promising cure and here the role of traditional systems of medicine cannot be overlooked. Ayurveda, the ancient science of life is enriched with ample amount of herbal drugs, which are tested and trusted and subjected to thorough clinical and experimental studies. The drugs have been proved safe and highly efficacious with almost no side effects and have been included in Pub-Med India and National Index of Medicine. A trial has been conducted as part of research program to evaluate the role and efficacy of ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) in the management of Hepatitis-B. Total 44 cases of Hepatitis-B were registered, out of which 38 cases completed the treatment schedule .The result of treatment were found satisfactory in terms of clinical and biochemical parameters. Moreover, Experimental Study has also been carried to substantiate the above clinical findings and also evaluate the mode of action of trial drug.

262. Takahashi, M., W. Li, K. Koike and K. Sadamoto (2010). "**Clinical effectiveness of KSS formula, a traditional folk remedy for alcohol hangover symptoms.**" Journal of Natural Medicines **64**(4): 487-491.

A formula (KSS formula) containing the pith of Citrus tangerine Hort. et Tanaka (Kitsuraku), the rhizome of ***Zingiber officinale*** (Shokyo), and brown sugar has been traditionally used in China for the treatment of discomfort and cold sensation in the abdomen after ingestion of large amounts of alcohol. Study evaluated the clinical effectiveness of this formula on signs and symptoms of alcohol hangover (AH). Of the twenty-two symptoms listed, significant decreases in severity scores were shown in nausea, vomiting, and diarrhea when the formula was administered in scheduled prophylactic doses. The score in overall well-being, ranging from 0 to 100 (worst possible condition), was 68.9 ± 16.5 (mean ± SD) in the control group and it decreased to 46.9 ± 27.3 and to 44.4 ± 26.4 in the two groups that included a dosing point prior to alcohol ingestion. Regardless of dosing schedules, KSS formula did not alter the time required for complete recovery from AH symptoms. These findings suggest the possibility that KSS formula may become a candidate for AH remedy when administered prophylactically.

263. Tandon, S., K. Gupta, S. Rao and K. Malagi (2010). "**Effect of *Triphala* mouthwash on the caries status.**" International Journal of Ayurveda Research **1**(2): 93–99.

Nearly 60–70% of the child Indian population suffers from dental caries. Mouth rinsing is the most cost effective method of preventing dental caries. '***Triphala***' (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***) has been a classic Ayurveda remedy, probably the best known among all Ayurvedic compounds. This study was conducted on 1501 students in the age group of 8-12 years with the aim of determining the effect of ***Triphala*** mouthwash on prevention of dental caries (manifest caries) as well as incipient carious lesions, and also comparing the effect of ***Triphala*** and chlorhexidine mouthwashes. The incipient caries was recorded at 3, 6, 9 months intervals and manifest caries at 9 months interval. No significant increase in the DMFS scores was found at the end of 9 months. Also, there was no significant increase in the incipient caries score towards the conclusion of the study. It was concluded that there was no significant difference between the ***Triphala*** and the chlorhexidine mouthwashes.

265. Terry, R., P. Posadzki, L. K. Watson and E. Ernst (2011). "**The use of Ginger (*Zingiber officinale*) for the treatment of pain: A systematic review of clinical trials.**" Pain Medicine **12**(12): 1808-1818.

Zingiber officinale, commonly known as ginger, has been widely used traditionally for a variety of medicinal purposes, one of which is for the treatment of pain. The aim of this systematic review was to evaluate the evidence from all human participant clinical trials that have assessed the efficacy of ginger for the treatment of any type of pain. Following a protocol, multiple databases were sought using comprehensive search strategies for *Z. officinale* and pain together with a trial filter for randomized or controlled clinical trials. Trials testing the efficacy of *Z. officinale*, used as a sole oral treatment against a comparison condition in human adults suffering from any pain condition, were included. Seven published articles, reporting a total of eight trials (481 participants), were included in the review. Six trials (two for osteoarthritis, one for dysmenorrhea, and three for experimentally induced acute muscle pain) found that the use of *Z. officinale* reduced subjective pain reports. The methodological quality of the included articles was variable. When assessed using the Jadad scale, which allows a score of between 0 and 5 to be given, included articles obtained Jadad ratings ranging from 2 to 5. Due to a paucity of well-conducted trials, evidence of the efficacy of *Z. officinale* to treat pain remains insufficient. However, the available data provide tentative support for the anti-inflammatory role of *Z. officinale* constituents, which may reduce the subjective experience of pain in some conditions such as osteoarthritis. Further rigorous trials therefore seem to be warranted.

266. Thomson, M., R. Corbin and L. Leung (2014). "**Effects of ginger for nausea and vomiting in early pregnancy: A meta-analysis.**" Journal of the American Board of Family Medicine **27**(1): 115-122.

Nausea and vomiting in early pregnancy (NVEP) is commonly encountered in family medicine. Ginger (***Zingiber officinale***) is a popular nonpharmacological treatment but consensus of its use is lacking. Methods: Authors conducted a meta-analysis of clinical trials using ginger for NVEP as published in PubMed and EMBASE, CINAHL,

Cochrane Library, and all EBM reviews. Studies satisfying 3 criteria were selected: (1) randomized placebo-controlled design; (2) use of ginger or *Z. officinale*; and (3) extractable data on improvement in NVEP. Data were synthesized into pooled odd ratios based on the random effects model, and results were tabulated with the aid of Forest plots. Results: identified 135 potentially relevant records; only 6 studies met the final criteria. Of the total 508 subjects, 256 and 252 subjects were randomly assigned to receive ginger and placebo, respectively. The use of ginger (~1 g daily) for at least 4 days is associated with a 5-fold likelihood of improvement in NVEP. Heterogeneity among the clinical studies were acknowledged in the final interpretation of results. Despite the widespread use of ginger in the diet, its clinic value and safety profile in treating NVEP is still unknown. This meta-analysis suggests that ginger is an effective nonpharmacological treatment for NVEP.

267. Umarji, M. P. and G. S. Jyothi (2013). "**Evaluation of efficacy and safety of a herbal formulation EveCare in the management of menstrual irregularities: Meta-analysis of 8 clinical studies.**" International Journal of Science and Research **4**(6): 475-481.

EveCare capsule is a polyherbal formulation that comprises extracts of *Saraca indica*, *Boerhaavia diffusa*, *Symplocos racemosa*, ***Tinospora cordifolia***, *Solanum nigrum*, *Aspargus racemosus*, *Aloe vera*, *Santalum album*, *Cyperus rotundus*, *Adhatoda vasica*, ***Triphala*** (***Emblica officinalis***, ***Terminalia bellirica***, ***Terminalia chebula***), Dashamoola, ***Trikatu Zingiber officinale, Piper longum, Piper nigrum***), and *Bombax malabaricum*; and powders of Kasisa, Godanti bhasma and Yashada bhasma. This is a meta-analysis of 8 clinical trials on EveCare in various menstrual irregularities. Inclusion criteria: Clinical studies, which evaluated the role of Evecare in various menstrual irregularities, were included in the meta-analysis. The outcome variables included measurement data on changes in clinical symptoms and signs, laboratory results, and incidence of adverse events during/after treatment. Exclusion criteria: Experimental, Phase I and Phase II clinical studies were excluded from the meta-analysis. The duration of treatment varied from 2 -3 months and in most of the studies, Evecare was given at a dose of 1-2 capsules twice daily or Evecare Syrup-10-15 ml twice daily. Present Meta -analysis of clinical studies indicate safety and efficacy of Evecare in normalizing menstrual irregularities, along with reduction in excessive menstrual bleeding and normalization of character and duration of menstrual flow. Improvement in anemia and altered hormonal levels was also noted in clinical studies.

268. Upadhyay, A. K., K. Kumar, A. Kumar and H. S. Mishra (2010). "***Tinospora cordifolia* (Willd.) Hook. f. and Thoms.(Guduchi)–validation of the Ayurvedic pharmacology through experimental and clinical studies.**" International Journal of Ayurveda Research **1**(2): 112.

Tinospora cordifolia locally known as Guduchi is a large, glabrous, perennial, deciduous, climbing shrub of weak and fleshy stem found throughout India. It is a widely used plant in folk and Ayurvedic systems of medicine. The chemical constituents reported from this shrub belong to different classes, such as alkaloids, diterpenoid lactones, glycosides, steroids, sesquiterpenoid, phenolics, aliphatic compounds and polysaccharides. Various properties of ***Tinospora cordifolia***, described in ancient texts of Ayurveda, like Rasayana, Sangrahi, Balya, Agnideepana,

Tridoshshamaka, Dahnashaka, Mehnashaka, Kasa-swasahara, Pandunashaka, Kamla-Kushta-Vataraktanashaka, Jwarhara, Krimihara, Prameha, Arshnashaka, Kricch-Hridroganashak, etc., are acquiring scientific validity through modern research adopting "reverse pharmacological" approach. Potential medicinal properties reported by scientific research include anti-diabetic, antipyretic, antispasmodic, anti-inflammatory, anti-arthritic, antioxidant, anti-allergic, anti-stress, anti-leprotic, antimalarial, hepato-protective, immuno-modulatory and anti-neoplastic activities. This review brings together various properties and medicinal uses of ***Tinospora cordifolia*** described in Ayurveda, along with phytochemical and pharmacological reports.

269. Vastrad, C. and R. Pakkanavar (2002). "**Clinical evaluation of PIL-28, a herbal formulation in the management of hemorrhoids.**" The Antiseptic **9**(99): 343-344.

Fifty patients of either sex aged between 22 and 63 years entered in the study for the evaluation of safety and efficacy of PIL-28. PIL-28 is a formulation of herbs and minerals designed for the management of hemorrhoids. PIL-28 contains powders of *Balsamodendron mukul*, Shilajeet (purified), *Melia azadirachta* and extracts of *Berberis aristata*, ***Emblica officinalis***, ***Terminalia chebula***, ***Terminalia bellirica***, *Cassia fistula*, *Bauhinia variegata* and *Mesua ferrea* processed in *Commelina salicifolia*, *Mimosa pudica*, *Acorus calamus*, *Blumea lacera*, *Caesalpinia bonducella* and *Amorphophallus campanulatus*. In the group that entered the study, 31 had external hemorrhoids, 10 had internal hemorrhoids and 9 of the patients had both internal as well as external hemorrhoids. The patients were given PIL-28 at a dose of 1 tablet, twice daily for 6 weeks. At the end of the 6 weeks treatment, the patients were evaluated for efficacy and tolerability of PIL-28 tablets. The results revealed that response to PIL-28 was very good in 56.25 % of patients and good in 37.50% of the patients, showing a marked improvement in general health along with a gross reduction of associated symptoms. There were no side effects observed during the treatment and follow-up period.

270. Vyjayanthi, G., S. Shetty, V. S. Saxena, P. D. Nadig, K. Venkateshwarlu, A. Serene, S. Sathyan, D. Bagchi and C. Kulkarni (2003). "**Randomized, double-blind, placebo-controlled trial of Aller-7 in patients with allergic rhinitis.**" Research Communications in Pharmacology and Toxicology **8**(1-2): IV-15-IV-24.

Allergic rhinitis (also known as "hay fever", "rose fever" or "summer catarrh") is the most frequently occurring immunological disorder, which affects men, women and children and imposes a significant cost in terms of suffering and productivity. Allergy is termed as an excessive reaction to a substance in the environment called an allergen. Pollen, mold, dust, mite and animal allergens that contact the nasal or eye lining cause sneezing, nasal congestion, and itchy, watery, swollen, red eyes. A broad spectrum of therapeutic options are available, however, the cure of allergic rhinitis appears to be far from satisfactory. Aller-7 is a unique combination of extracts from seven medicinal plants including ***Phyllanthus emblica***, ***Terminalia chebula***, ***Terminalia bellirica***, *Albizia lebbeck,* ***Piper nigrum***, ***Zingiber officinale*** *and* ***Piper longum***. A novel, polyherbal formulation (Aller-7) comprising of seven novel medicinal herbal extracts were assessed in a double-blind, placebo-controlled clinical trial in 48 patients (23 males & 25 females) ages 20-45 yrs for a period of 3 months to

evaluate its activity in patients suffering from allergic rhinitis. The major symptoms of allergic rhinitis were significantly reduced, while the assessment on the quality of life revealed improvement in 70% of the patients in the Aller-7 supplemented group. Comparison of the nasal and non-nasal symptoms of the Aller-7 and placebo groups showed improvement during the third month in the Aller-7 group as compared to placebo.

271. Viljoen, E., J. Visser, N. Koen and A. Musekiwa (2014). "**A systematic review and meta-analysis of the effect and safety of ginger in the treatment of pregnancy-associated nausea and vomiting.**" Nutrition Journal **13**(1).

Nausea and vomiting during pregnancy (NVP) occur commonly. Possible harmful side-effects of conventional medicine to the fetus create the need for alternative options to relieve NVP. This systematic review (SR) investigated current evidence regarding orally administered ginger (***Zingiber officinale***) for the treatment of NVP. The primary objective was to assess the effectiveness of ginger in treating NVP. The secondary objective was to assess the safety of ginger during pregnancy. A comprehensive electronic bibliographic database search was carried out. Randomized controlled trials (RCTs) of the efficacy of orally administered ginger, as treatment for NVP in pregnant women at any stage of pregnancy, published in English, were included. Two researchers independently extracted data and assessed trial quality. RevMan5 software (Cochrane Collaboration) was used for data analysis. p < 0.05 was considered statistically significant. Results: Twelve RCTs involving 1278 pregnant women were included. Ginger significantly improved the symptoms of nausea when compared to placebo (MD 1.20, 95% CI 0.56-1.84, p = 0.0002, I2 = 0%). Ginger did not significantly reduce the number of vomiting episodes during NVP, when compared to placebo, although there was a trend towards improvement (MD 0.72, 95% CI -0.03-1.46, p = 0.06, I2 = 71%). Subgroup analyses seemed to favor the lower daily dosage of 1500 mg ginger for nausea relief. Ginger did not pose a significant risk for spontaneous abortion compared to placebo (RR 3.14, 95% CI 0.65-15.11, p = 0.15; I2 = 0%), or to vitamin B6 (RR 0.49, 95% CI 0.17-1.42, p = 0.19, I2 = 40%). Similarly, ginger did not pose a significant risk for the side-effects of heartburn or drowsiness. This review suggests potential benefits of ginger in reducing nausea symptoms in pregnancy (bearing in mind the limited number of studies, variable outcome reporting and low quality of evidence). Ginger did not significantly affect vomiting episodes, nor pose a risk for side-effects or adverse events during pregnancy. Based on evidence from this SR, ginger could be considered a harmless and possibly effective alternative option for women suffering from NVP. International Prospective Register of Systematic Reviews (PROSPERO) registration number: CRD42011001237.

272. Visalyaputra, S., N. Petchpaisit, K. Somcharoen and R. Choavaratana (1998). "**The efficacy of ginger root in the prevention of postoperative nausea and vomiting after outpatient gynaecological laparoscopy.**" Anaesthesia **53**(5): 506-510.

To determine the anti-emetic effect of ginger (***Zingiber officinale***) as compared to droperidol, 120 patients scheduled to have gynaecological diagnostic laparoscopy as day cases were randomly allocated into placebo, droperidol, ginger and ginger plus droperidol groups to receive either 2 g of ginger or 1.25 mg of droperidol or both.

There were no significant differences in the incidences of postoperative nausea which were 32%, 20%, 22% and 33%, and vomiting which were 35%, 15%, 25% and 25% in the four groups, respectively. Authors conclude that ginger powder, in the dose of 2 g, droperidol 1.25 mg or both are ineffective in reducing the incidence of postoperative nausea and vomiting after day case gynaecological laparoscopy.

273. Vishwas, N. A. and K. K. Raj (2013). "**An ayurvedic polyherbal formulation PDBT for dyslipidemia and prevention of coronary artery disease (CAD) in pre-diabetic individuals.**" International Journal of Research in Ayurveda and Pharmacy **4**(5): 701-704.

Pre-diabetes is a 'grey area' between normal and diabetes. Various studies have shown that pre-diabetic subjects who developed diabetes had higher triglyceride and cholesterol values at baseline. At the time of diagnosis of diabetes around half of the patients will show some evidence of coronary artery disease. Treating dyslipidaemia in pre diabetes condition can not only reduce the conversion rate to diabetes but also occurrence of coronary artery disease (CAD). The Purpose of present study was to see whether an Ayurvedic polyherbal formulation PDBT which contains water extracts of Guduchi (***Tinospora cordifolia***), Vijaysar (*Pterocarpus marsupium*), Gudmar (*Gymnemma sylvestre*), Karvellak (*Momordica charantia*) and Shunthi (***Zingiber officinale***) can reduce mild to moderate dyslipidaemia in Pre-diabetic state as compared to placebo. A double blind placebo controlled (Randomized Controlled Trial) RCT was conducted on 100 patients (50 in each group) having mean age 48.78 ± 10.098; for 6 months to see the effect of polyherbal formulation as compared to placebo in pre-diabetic individuals. A diagnostic criterion for pre-diabetes was set according American Diabetic Association (ADA) 2000. Cholesterol, High Density Lipoprotein (HDL), was done with Wyebenga and Pileggi's method / Bio-lab Kit. Triglycerides were estimated by enzymatic Kit method. Blood sugar level (BSL) was calculated by Glucose oxidase- peroxidase (GOD-POD) method. Low Density lipoprotein (LDL), Very Low Density Lipoprotein (VLDL) was calculated by formula. These investigations were done before treatment (BT) and after treatment (AT). Unpaired T and paired T test were applied by INSTAT 2 software as a test of significance. Mean Cholesterol before treatment and after treatment 200.04 ± 41.6 and 172.09 ± 42.29, Mean HDL before treatment and after treatment 44.544 ± 10.517 and 47.30 ± 8.35, Mean LDL 116.37 and 92.91. Triglycerides before treatment and A. T. 160.16 ± 132.02 in PDBT treated group. While in placebo treated group these values were increased from 170.53 ± 32.05 to 191.62 ± 36.75, for Cholesterol before treatment and after treatment. LDL increased from 92.85 ± 31.19 to 99.139 for LDL. While for triglycerides values increased from 165.75 ± 44.33 to 211.18 ± 46.7.

274. Vutyavanich, T., T. Kraisarin and R.-a. Ruangsri (2001). "**Ginger for nausea and vomiting in pregnancy: randomized, double-masked, placebo-controlled trial.**" Obstetrics & Gynecology **97**(4): 577-582.

Objective was to determine the effectiveness of ginger (***Zingiber officinale***) for the treatment of nausea and vomiting of pregnancy. Women with nausea and vomiting of pregnancy, who first attended an antenatal clinic at or before 17 weeks' gestation, were invited to participate in the study. During a 5-month period, 70 eligible women gave consent and were randomized in a double-masked design to receive either oral ginger 1 g per day or an identical placebo for 4 days. Subjects graded the severity of

their nausea using visual analog scales and recorded the number of vomiting episodes in the previous 24 hours before treatment, and again during 4 consecutive days while taking treatment. At a follow-up visit 7 days later, five-item Likert scales were used to assess the severity of their symptoms. All participants except three in the placebo group remained in the study. The visual analog scores of posttherapy minus baseline nausea decreased significantly in the ginger group (2.1 ± 1.9) compared with the placebo group (0.9 ± 2.2, P = .014). The number of vomiting episodes also decreased significantly in the ginger group (1.4 ± 1.3) compared with the placebo group (0.3 ± 1.1, P < .001). Likert scales showed that 28 of 32 in the ginger group had improvement in nausea symptoms compared with 10 of 35 in the placebo group (P < .001). No adverse effect of ginger on pregnancy outcome was detected. Ginger is effective for relieving the severity of nausea and vomiting of pregnancy.

275. Vyas, P., H. Chandola, F. Ghanchi and S. Ranthem (2012). "**Clinical evaluation of Rasayana compound as an adjuvant in the management of tuberculosis with anti-Koch's treatment.**" AYU **33**(1): 38-43.

Tuberculosis (TB) continues to intimidate the human race since time immemorial not only due to its effects as a medical malady, but also by its impact as a social and economic tragedy. At the dawn of the new millennium, we are still mute witnesses to the silent yet efficient march of this sagacious disease, its myriad manifestations and above all its unequalled, vicious power. Through the millennia, TB never ever disappeared from the developing world. In 1991, the World Health Assembly (WHA) resolution recognized TB as a major global public health problem. The DOTS strategy was launched in 1994, and became the global recommended strategy for TB control since then. The study was conducted on 133 patients of TB (Category-I) selected from 1) I.P.G.T. and R. A. Hospital, Gujarat Ayurved University, Jamnagar, 2) District Tuberculosis Centre and Hospital, Jamnagar and 3) Guru Govind Singh Hospital, P. N. Marg, Jamnagar. They were randomly divided into two groups irrespective to sex and religion. The study is a single blind controlled study. The present study deals with clinical evaluation of Rasayana drugs considering of Amalaki (***Emblica officinalis*** Gaertn.), Guduchi (***Tinospora cordifolia*** willd.), Ashwagandha (***Withania somnifera*** L.) Dunal, Yastimadhu (*Glycyrrhiza glabra* Linn.), Pippali (***Piper longum*** Linn.), Sariva (*Hemidesmus indicus* R.Br.), Kustha (*Saussurea lappa* Falc.), Haridra (*Curcuma longa* Linn.) and Kulinjan (*Alpinia galangal* Linn.) as an adjuvant therapy with anti-Koch's treatment. The results obtained revealed that Rasayana compound was found to decrease cough (83%), fever (93%), dyspnea (71.3%), hemoptysis (87%) and increase body weight (7.7%) with statistically highly significant (P<0.001).

276. Vyjayanthi, G., S. Shetty, V. S. Saxena, P. D. Nadig, K. Venkateshwarlu, A. Serene, S. Sathyan, D. Bagchi and C. Kulkarni (2003). "**Randomized, double-blind, placebo-controlled trial of Aller-7 in patients with allergic rhinitis.**" Research Communications in Pharmacology and Toxicology **8**(1-2): IV-15-IV-24.

Allergic rhinitis (also known as "hay fever", "rose fever" or "summer catarrh") is the most frequently occurring immunological disorder, which affects men, women and children and imposes a significant cost in terms of suffering and productivity. Allergy is termed as an excessive reaction to a substance in the environment called an

allergen. Pollen, mold, dust, mite and animal allergens that contact the nasal or eye lining cause sneezing, nasal congestion, and itchy, watery, swollen, red eyes. A broad spectrum of therapeutic options are available, however, the cure of allergic rhinitis appears to be far from satisfactory. A novel, polyherbal formulation (Aller-7) of herbal extracts were assessed in a double-blind, placebo-controlled clinical trial in 48 patients (23 males & 25 females) ages 20-45 yrs for a period of 3 months to evaluate its activity in patients suffering from allergic rhinitis. Aller-7 is a unique combination of extracts from seven medicinal plants including ***Phyllanthus emblica***, ***Terminalia chebula***, ***Terminalia bellirica***, *Albizia lebbeck*, ***Piper nigrum***, ***Zingiber officinale*** *and* ***Piper longum***. The major symptoms of allergic rhinitis were significantly reduced, while the assessment on the quality of life revealed improvement in 70% of the patients in the Aller-7 supplemented group. Comparison of the nasal and non-nasal symptoms of the Aller-7 and placebo groups showed improvement during the third month in the Aller-7 group as compared to placebo.

277. Willetts, K. E., A. Ekangaki and J. A. Eden (2003). "**Effect of a ginger extract on pregnancy-induced nausea: A randomised controlled trial.**" Australian and New Zealand Journal of Obstetrics and Gynaecology **43**(2): 139-144.

Objective was to investigate the effect of a ginger (***Zingiber officinale***) extract (EV.EXT35) on the symptoms of morning sickness. Double-blind randomised placebo-controlled trial. Setting: A tertiary metropolitan teaching hospital, March 1999-November 1999. The participants included 120 women less than 20 weeks pregnant, who had experienced morning sickness daily for at least a week and had had no relief of symptoms through dietary changes. Intervention: Random allocation of 125 mg ginger extract (EV.EXT35; equivalent to 1.5 g of dried ginger) or placebo given four times per day for 4 days. Main outcome measures were taken as nausea, vomiting and retching as measured by the Rhodes Index of Nausea, Vomiting and Retching. The nausea experience score was significantly less for the ginger extract group relative to the placebo group after the first day of treatment and this difference was present for each treatment day. Retching was also reduced by the ginger extract although to a lesser extent. No significant effect was observed on vomiting. Follow-up of the pregnancies revealed normal ranges of birthweight, gestational age, Apgar scores and frequencies of congenital abnormalities when the study group infants were compared to the general population of infants born at the Royal Hospital for Women for the year 1999-2000. Ginger can be considered as a useful treatment option for women suffering from morning sickness.

278. Wilson, P. B. (2015). "**Ginger (*Zingiber officinale*) as an analgesic and ergogenic aid in sport: A systemic review.**" Journal of Strength and Conditioning Research **29**(10): 2980-2995.

Ginger (***Zingiber officinale***) is a popular spice used to treat a variety of maladies, including pain. Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently used by athletes to manage and prevent pain; unfortunately, NSAIDs contribute to substantial adverse effects, including gastrointestinal (GI) dysfunction, exercise-induced bronchoconstriction, hyponatremia, impairment of connective tissue remodeling, endurance competition withdrawal, and cardiovascular disease. Ginger, however, may act as a promoter of GI integrity and as a bronchodilator. Given these potentially

positive effects of ginger, a systematic review of randomized trials was performed to assess the evidence for ginger as an analgesic and ergogenic aid for exercise training and sport. Among 7 studies examining ginger as an analgesic, the evidence indicates that roughly 2 $g \cdot d^{-1}$ of ginger may modestly reduce muscle pain stemming from eccentric resistance exercise and prolonged running, particularly if taken for a minimum of 5 days. Among 9 studies examining ginger as an ergogenic aid, no discernable effects on body composition, metabolic rate, oxygen consumption, isometric force generation, or perceived exertion were observed. Limited data suggest that ginger may accelerate recovery of maximal strength after eccentric resistance exercise and reduce the inflammatory response to cardiorespiratory exercise. Major limitations to the research include the use of untrained individuals, insufficient reporting on adverse events, and no direct comparisons with NSAID ingestion. While ginger taken over 1-2 weeks may reduce pain from eccentric resistance exercise and prolonged running, more research is needed to evaluate its safety and efficacy as an analgesic for a wide range of athletic endeavors.

279. Yip, Y. B. and A. C. Y. Tam (2008). "**An experimental study on the effectiveness of massage with aromatic ginger and orange essential oil for moderate-to-severe knee pain among the elderly in Hong Kong.**" Complementary Therapies in Medicine **16**(3): 131-138.

Objectives were to assess the efficacy of an aromatic essential oil (1% ***Zingiber officinale*** and 0.5% *Citrus sinesis*) massage among the elderly with moderate-to-severe knee pain. Fifty-nine older persons were enrolled in a double-blind, placebo-controlled experimental study group from the Community Centre for Senior Citizens, Hong Kong. The intervention was six massage sessions with ginger and orange oil over a 3-week period. The placebo control group received the same massage intervention with olive oil only and the control group received no massage. Assessment was done at baseline, post 1-week and post 4 weeks after treatment. Changes from baseline to the end of treatment were assessed on knee pain intensity, stiffness level and physical functioning (by Western Ontario and McMaster Universities Osteoarthritis index) and quality of life (by SF-36). There were significant mean changes between the three time-points within the intervention group on three of the outcome measures: knee pain intensity ($p = 0.02$); stiffness level ($p = 0.03$); and enhancing physical function ($p = 0.04$) but these were not apparent with the between-groups comparison ($p = 0.48$, 0.14 and 0.45 respectively) 4 weeks after the massage. The improvement of physical function and pain were superior in the intervention group compared with both the placebo and the control group at post 1-week time (both $p = 0.03$) but not sustained at post 4 weeks ($p = 0.45$ and 0.29). The changes in quality of life were not statistically significant for all three groups. The aroma-massage therapy seems to have potential as an alternative method for short-term knee pain relief.

280. Zahmatkash, M. and M. R. Vafaeenasab (2011). "**Comparing analgesic effects of a topical herbal mixed medicine with salicylate in patients with knee osteoarthritis.**" Pakistan Journal of Biological Sciences **14**(13): 715-719.

Knee osteoarthritis is the most common cause of disability among people and it is a common disease of joints that can lead to cartilage damage. In this study the

analgesic effects of a herbal ointment containing cinnamon, ginger (***Zingiber officinale***), mastic (Saghez) and sesame oil is compared with Salicylate ointment in patients suffering from knee osteoarthritis. It was a double-blind randomized controlled trail study. Patients with diagnosed arthritis were involved in the study and they were divided in two groups via block randomization method. For six weeks, twice a day, intervention group applied herbal ointment and control group used Salicylate ointment. The severity of pain, morning stiffness and limited motion were measured using Visual Analog Pain Scale. In order to analyze the trends of these three indexes, repeated measurement test was used. Ninety two participates with the mean age of 52.2 (±12.4) years and with the mean disease period of 30.45 (±30.3) months were involved in the study. There was no significant difference between two groups regarding the distribution of sex, weight, height, BMI and the duration of illness. No statistical difference was observed between two groups regarding pain relief, morning stiffness and limited motion; nevertheless in repeated measurements during second, forth and sixth weeks in both groups the decreasing trend of these three indexes had been statistically significant ($p<0.0001$). It seems that using this herbal combination is clinically effective for patients suffering from knee osteoarthritis in order to decrease their pain, morning stiffness and limited motion; its effect is comparable with Salicylate ointment.

281. Zahra, Y., S. Tehmina, F. Nudrat and R. Zakir ur (2007). "**Pharmacological and clinical evaluation of herbal formulation for the treatment of various hair/scalp problems.**" Pakistan Journal of Scientific and Industrial Research **50**(2): 113-117.

A product formulated from 9 herbs (Acacia concinna pods, ***Emblica officinalis*** syn. ***Phyllanthus emblica*** dried fruits, Nardostachys jatamansi rhizomes, ***Terminalia chebula*** dried fruits, ***Terminalia bellirica*** dried fruits, *Nigella sativa* seeds, *Trigonella foenum-graecum* seeds, *Lagenaria vulgaris* [L. siceraria] seeds, and *Lawsonia alba* [Lawsonia inermis] dried leaves) in a sesamum oil base supplemented with 4 essential oils and vitamin E was evaluated for its efficacy in the treatment of hair/scalp problems. The clinical study was conducted on 175 human volunteers suffering from different kinds of hair and scalp problems. After 2-10 weeks, this formulation was highly effective against head pustules, dryness and brittleness of hair, dandruff, itching, split hair, excessive hair fall, and poor hair growth. The formulation was also effective against headache and sleeplessness. The results of acute oral toxicity test, dermal irritant test and eye irritation test revealed that the product was safe and non-toxic, and had no side effect.

282. Zakeri, Z., S. Izadi, Z. Bari, F. Soltani, B. Narouie and M. Ghasemi-Rad (2011). "**Evaluating the effects of ginger extract on knee pain, stiffness and difficulty in patients with knee osteoarthritis.**" Journal of Medicinal Plants Research **5**(15): 3375-3379.

The present study was aimed to evaluate the effects of ginger (***Zingiber officinale***) extract on knee pain, stiffness and difficulty in patients with knee osteoarthritis. 204 patients with knee osteoarthritis were enrolled in a randomized clinical trial. After a 1-week washing period, the groups received ginger extract (103 cases) or placebo (101 cases). A responder was defined by a reduction in pain of > 15 mm on a visual analog scale (VAS) or by 20% reduction in the mean score of each index of the Western Ontario and Mc Master Universities (WOMAC) criteria after 6 weeks. Pain reduction

according to VAS was more significant in ginger group than placebo ($p<0.05$). Although pain reduction according to WOMAC was greater in ginger than placebo group, the difference was not statistically significant. Reduction in morning stiffness and difficulty were statistically greater in the ginger than the placebo group ($p<0.05$). Also there was no difference between the two groups in side effects of therapy. In conclusion, the results showed that ginger extract is effective in reducing pain, stiffness and difficulty in patients with knee osteoarthritis, therefore is recommended as a safe drug for these patients.

283. Zick, S. M., D. K. Turgeon, J. Ren, M. T. Ruffin, B. D. Wright, A. Sen, Z. Djuric and D. E. Brenner (2015). "**Pilot clinical study of the effects of ginger root extract on eicosanoids in colonic mucosa of subjects at increased risk for colorectal cancer.**" Molecular Carcinogenesis **54**(9): 908-915.

Colorectal cancer (CRC) remains a significant cause of mortality. Inhibitors of cyclooxygenase (COX) and thus prostaglandin E2, are promising CRC preventives, but have significant toxicities. Ginger (***Zingiber officinale***) has been shown to inhibit COX, to decrease the incidence and multiplicity of adenomas, and decrease PGE2 concentrations in subjects at normal risk for CRC. This study was conducted to determine the effects of 2.0g/d of ginger given orally on the levels of PGE2, leukotriene B4 (LTB4), 13-hydroxy-octadecadienoic acids, and 5-, 12-, & 15-hydroxyeicosatetraenoic acid, in the colonic mucosa of subjects at increased risk for CRC. Authors randomized 20 subjects to 2.0g/d *ginger* or placebo for 28 d. At baseline and Day 28, a flexible sigmoidoscopy was used to obtain colon biopsies. A liquid chromatography mass spectrometry method was used to determine eicosanoid levels in the biopsies, and levels were expressed per amount of protein or free arachidonic acid (AA). There was a significant decrease in AA between baseline and Day 28 ($P=0.05$) and significant increase in LTB4 ($P=0.04$) when normalized to protein, in subjects treated with ginger versus placebo. No other changes in eicosanoids were observed. There was no difference between the groups in total adverse events (AE; $P=0.06$). Ginger lacks the ability to decrease eicosanoid levels in people at increased risk for CRC. Ginger did appear to be both tolerable and safe; and could have chemopreventive effects through other mechanisms. Further investigation should focus on other markers of CRC risk in those at increased CRC risk.