High Potency Ginger Extract Reduces Menstrual Discomfort in Healthy Participants with Recurrent Dysmenorrhea Linked to Hypercontractility of the Uterus: a Randomized, Double-Blind, Placebo-Controlled Trial

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Abstract

Ginger has been widely used for human health yet lack of standardization and poor stability has limited its health applications. This clinical study investigated the efficacy and safety of GINFORT® a ginger extract standardised to >26% gingeroids vs. placebo in primary dysmenorrhea subjects. Fifty female subjects aged between 18 to 35 years with primary dysmenorrhea were enrolled. Participants received either GINFORT® or placebo. The primary endpoint included maximum dysmenorrheic pain VAS score and secondary endpoints included verbal multidimensional scoring system (VMS), evaluation of symptoms reported during menstruation, rescue medication consumption, and subject's overall satisfaction. There was a significant improvement in the mean VAS score, VMS grade, and symptoms reported during menstruation in GINFORT® group compared to placebo. It was also found to be safe and well tolerated. The findings of this study indicated that GINFORT® is an effective botanical option for women with primary dysmenorrhea.

Keywords: Ginger; Menstrual Discomfort; Primary Dysmenorrhea; VAS; VMS

ZENZERO

Fitoterapia. 2011 Jan;82(1):38-43. doi: 10.1016/j.fitote.2010.09.004. Epub 2010 Sep 15.
Cyclooxygenase-2 inhibitors in ginger (Zingiber officinale).
van Breemen RB, Tao Y, Li W.
Abstract
Ginger roots have been used to treat inflammation and have been reported to inhibit cyclooxygenase (COX). Ultrafiltration liquid chromatography mass spectrometry was used to screen a chloroform partition of a methanol extract of ginger roots for COX-2 ligands, and 10-gingerol, 12-gingerol, 8-shogaol, 10-shogaol, 6-gingerdione, 8-gingerdione, 10-gingerdione, 6-dehydro-10-gingerol, 6-paradol, and 8-paradol bound to the enzyme active site. Purified 10-gingerol, 8-shogaol and 10-shogaol inhibited COX-2 with IC(50) values of 32 μM, 17.5 μM and 7.5 μM, respectively. No inhibition of COX-1 was detected. Therefore, 10-gingerol, 8-shogaol and 10-shogaol inhibit COX-2 but not COX-1, which can explain, in part, the anti-inflammatory properties of ginger.

ISRN Obstet Gynecol. 2014 May 4;2014:792708. doi: 10.1155/2014/792708. eCollection 2014.

Effect of treatment with ginger on the severity of premenstrual syndrome symptoms.

Khayat S, Kheirkhah M, Behboodi Moghadam Z, Fanaei H, Kasaeian A, Javadimehr M.

Abstract

Premenstrual syndrome (PMS) is a common disorder. Although the etiology of PMS is not clear, to relieve from this syndrome different methods are recommended. One of them is use of medicinal herbs. This study was carried out to evaluate effects of ginger on severity of symptoms of PMS. This study was a clinical trial, double-blinded work, and participants were randomly allocated to intervention (n = 35) and control (n = 35) groups. To determine persons suffering from PMS, participants completed daily record scale questionnaire for two consecutive cycles. After identification, each participant received two ginger capsules daily from seven days before menstruation to three days after menstruation for three cycles and they recorded severity of the symptoms by daily record scale questionnaire. Data before intervention were compared with date 1, 2, and 3 months after intervention. Before intervention, there were no significant differences between the mean scores of PMS symptoms in the two groups, but after 1, 2, and 3 months of treatment, there was a significant difference between the two groups ($P < 0.0001$). Based on the results of this study, maybe ginger is effective in the reduction of severity of mood and physical and behavioral symptoms of PMS and we suggest ginger as treatment for PMS.

Evid Based Complement Alternat Med. 2016;2016:6295737. doi: 10.1155/2016/6295737. Epub 2016 May 5.

Efficacy of Oral Ginger (Zingiber officinale) for Dysmenorrhea: A Systematic Review and Meta-Analysis.

Chen CX, Barrett B, Kwekkeboom KL.

Abstract

This systematic review examines the efficacy of oral ginger for dysmenorrhea. Key biomedical databases and grey literature were searched. We included randomized controlled trials comparing oral ginger against placebo or active treatment in women with dysmenorrhea. Six trials were identified. Two authors independently reviewed the articles, extracted data, and assessed risk of bias. Discrepancies were resolved by consensus with a third reviewer. We completed a narrative synthesis of all six studies and exploratory meta-analyses of three studies comparing ginger with placebo and two studies comparing ginger with a nonsteroidal anti-inflammatory drug (NSAID). Ginger appeared more effective for reducing pain severity than placebo. The weighted mean difference on a 10 cm visual analogue scale was 1.55 cm (favoring ginger) (95% CI 0.68 to 2.43). No significant difference was found between ginger and mefenamic acid (an NSAID). The standardized mean difference was 0 (95% CI -0.40 to 0.41). Available data suggest that oral ginger could be an effective treatment for menstrual pain in dysmenorrhea. Findings, however, need to be interpreted with caution because of the small number of studies, poor methodological quality of the studies, and high heterogeneity across trials. The review highlights the need for future trials with high methodological quality.

Pain Med. 2015 Dec;16(12):2243-55. doi: 10.1111/pme.12853. Epub 2015 Jul 14.

Efficacy of Ginger for Alleviating the Symptoms of Primary Dysmenorrhea: A Systematic Review and Meta-analysis of Randomized Clinical Trials.

Daily JW, Zhang X, Kim da S, Park S.

Abstract

OBJECTIVE:

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.

METHODS:

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).

RESULTS:

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 of risk of bias.

CONCLUSION:

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.

J Pak Med Assoc. 2013 Jan;63(1):8-10.

The effect of ginger for relieving of primary dysmenorrhoea.

Jenabi E.

Abstract

OBJECTIVE:

To assess the effectiveness of ginger in providing relief to patients of primary dysmenorrhoea.

METHODS:

The clinical trial was conducted at Toyserkan Azad University in western Iran from July 10 to September 5, 2010. It comprised of 70 female students of the university with primary dysmenorrhoea.The subjects were randomly divided in to two equal groups and were given either placebo or ginger in capsule form for 3 days in first menstruation cycles. They graded the severity of their pain using a visual analogue scale. A 5-point Likert scale was used to assess response to treatment. Wilcoxor's rank-sum test was used to compare the severity of pain in the two groups.

RESULTS:

Compared with the baseline, the decrease in the visual analogue scores of post-therapy pain in the ginger group was significantly greater than that for placebo group. In the ginger group, 29 (82.85%) subjects reported an improvement in nausea symptoms, compared with 16 (47.05%) in the placebo group.

CONCLUSION:

Ginger is effective in minimising the pain severity in primary dysmenorrhoea.

J Altern Complement Med. 2009 Feb;15(2):129-32. doi: 10.1089/acm.2008.0311.

Comparison of effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea.

Ozgoli G, Goli M, Moattar F.

Abstract

OBJECTIVES:

To compare the effects of ginger, mefenamic acid, and ibuprofen on pain in women with primary dysmenorrhea.

METHODS:

This was a double-blind comparative clinical trial conducted from September 2006 to February 2007. Participants were 150 students (18 years old and over) with primary dysmenorrhea from the dormitories of two medical universities who were alternately divided into three equal groups. Students in the ginger group took 250 mg capsules of ginger rhizome powder four times a day for three days from the start of their menstrual period. Members of the other groups received 250 mg mefenamic acid or 400 mg ibuprofen capsules, respectively, on the same protocol. A verbal multidimensional scoring system was used for assessing the severity of primary dysmenorrhea. Severity of disease, pain relief, and satisfaction with the treatment were compared between the groups after one menstruation.

RESULTS:

There were not significant differences between groups in baseline characteristics, $p > 0.05$. At the end of treatment, severity of dysmenorrhea decreased in all groups and no differences were found between the groups in severity of dysmenorrhea, pain relief, or satisfaction with the treatment, $p > 0.05$. No severe side effects occurred.

CONCLUSION:

Ginger was as effective as mefenamic acid and ibuprofen in relieving pain in women with primary dysmenorrhea. Further studies regarding the effects of ginger on other symptoms associated with dysmenorrhea and efficacy and safety of various doses and treatment durations of ginger are warranted.

BOSWELLIA

Curr Med Chem. 2006;13(28):3359-69.
Boswellic acids: biological actions and molecular targets.
Poeckel D, Werz O.
Abstract
Gum resin extracts of Boswellia species have been traditionally applied in folk medicine for centuries to treat various chronic inflammatory diseases, and experimental data from animal models and studies with human subjects confirmed the potential of B. spec extracts for the treatment of not only inflammation but also of cancer. Analysis of the ingredients of these extracts revealed that the pentacyclic triterpenes boswellic acids (BAs) possess biological activities and appear to be responsible for the respective pharmacological actions. Approaches in order to elucidate the molecular mechanisms underlying the biological effects of BAs identified 5-lipoxygenase, human leukocyte elastase, toposiomerase I and II, as well as IkappaB kinases as molecular targets of BAs. Moreover, it was shown that depending on the cell type and the structure of the BAs, the compounds differentially interfere with signal transduction pathways including Ca(2+/-) and MAPK signaling in various blood cells, related to functional cellular processes important for inflammatory reactions and tumor growth. This review summarizes the biological actions of BAs on the cellular and molecular level and attempts to put the data into perspective of the beneficial effects manifested in animal studies and trials with human subjects related to inflammation and cancer.

Planta Med. 2006 Oct;72(12):1100-16.
Boswellic acids in chronic inflammatory diseases.
Ammon HP.
Abstract
Oleogum resins from BOSWELLIA species are used in traditional medicine in India and African countries for the treatment of a variety of diseases. Animal experiments showed anti-inflammatory activity of the extract. The mechanism of this action is due to some boswellic acids. It is different from that of NSAID and is related to components of the immune system. The most evident action is the inhibition of 5-lipoxygenase. However, other factors such as cytokines (interleukins and TNF-alpha) and the complement system are also candidates. Moreover, leukocyte elastase and oxygen radicals are targets. Clinical studies, so far with pilot character, suggest efficacy in some autoimmune diseases including rheumatoid arthritis, Crohn's disease, ulcerative colitis and bronchial asthma. Side effects are not severe when compared to modern drugs used for the treatment of these diseases.

Indian J Pharm Sci. 2011 May;73(3):255-61. doi: 10.4103/0250-474X.93507.

Boswellia serrata, a potential antiinflammatory agent: an overview.

Siddiqui MZ.

Abstract

The resin of Boswellia species has been used as incense in religious and cultural ceremonies and in medicines since time immemorial. Boswellia serrata (Salai/Salai guggul), is a moderate to large sized branching tree of family Burseraceae (Genus Boswellia), grows in dry mountainous regions of India, Northern Africa and Middle East. Oleo gum-resin is tapped from the incision made on the trunk of the tree and is then stored in specially made bamboo basket for removal of oil content and getting the resin solidified. After processing, the gum-resin is then graded according to its flavour, colour, shape and size. In India, the States of Andhra Pradesh, Gujarat, Madhya Pradesh, Jharkhand and Chhattisgarh are the main source of Boswellia serrata. Regionally, it is also known by different names. The oleo gum-resins contain 30-60% resin, 5-10% essential oils, which are soluble in the organic solvents, and the rest is made up of polysaccharides. Gum-resin extracts of Boswellia serrata have been traditionally used in folk medicine for centuries to treat various chronic inflammatory diseases. The resinous part of Boswellia serrata possesses monoterpenes, diterpenes, triterpenes, tetracyclic triterpenic acids and four major pentacyclic triterpenic acids i.e. β-boswellic acid, acetyl-β-boswellic acid, 11-keto-β-boswellic acid and acetyl-11-keto-β-boswellic acid, responsible for inhibition of pro-inflammatory enzymes. Out of these four boswellic acids, acetyl-11-keto-β-boswellic acid is the most potent inhibitor of 5-lipoxygenase, an enzyme responsible for inflammation.

Clin Pharmacokinet. 2011 Jun;50(6):349-69. doi: 10.2165/11586800-000000000-00000.

Boswellia serrata: an overall assessment of in vitro, preclinical, pharmacokinetic and clinical data.

Abdel-Tawab M, Werz O, Schubert-Zsilavecz M.

Abstract

Non-steroidal anti-inflammatory drug (NSAID) intake is associated with high prevalence of gastrointestinal or cardiovascular adverse effects. All efforts to develop NSAIDs that spare the gastrointestinal tract and the cardiovasculature are still far from achieving a breakthrough. In the last two decades, preparations of the gum resin of Boswellia serrata (a traditional ayurvedic medicine) and of other Boswellia species have experienced increasing popularity in Western countries. Animal studies and pilot clinical trials support the potential of B. serrata gum resin extract (BSE) for the treatment of a variety of inflammatory diseases like inflammatory bowel disease, rheumatoid arthritis, osteoarthritis and asthma. Moreover, in 2002 the European Medicines Agency classified BSE as an 'orphan drug' for the treatment of peritumoral brain oedema. Compared to NSAIDs, it is expected that the administration of BSE is associated with better tolerability, which needs to be confirmed in further clinical trials. Until recently, the pharmacological effects of BSE were mainly attributed to suppression of leukotriene formation via inhibition of 5-lipoxygenase (5-LO) by two boswellic acids, 11-keto-β-boswellic acid (KBA) and acetyl-11-keto-β-boswellic acid (AKBA). These two boswellic acids have also been chosen in the monograph of Indian frankincense in European Pharmacopoiea 6.0 as markers to ensure the quality of the air-dried gum resin exudate of B. serrata. Furthermore, several dietary supplements advertise the enriched content of KBA and AKBA. However, boswellic acids failed to inhibit leukotriene formation in human whole blood, and pharmacokinetic data revealed very low concentrations of AKBA and KBA in plasma, being far below the effective concentrations for bioactivity in vitro. Moreover, permeability studies suggest poor absorption of AKBA following oral administration. In view of these results, the previously assumed mode of action - that is, 5-LO inhibition - is questionable. On the other hand, 100-fold higher plasma concentrations have been determined for β-boswellic acid, which inhibits microsomal prostaglandin E synthase-1 and the serine protease cathepsin G. Thus, these two enzymes might be reasonable molecular targets related to the anti-inflammatory properties of BSE. In view of the results of clinical trials and the experimental data from in vitro studies of BSE, and the available pharmacokinetic and metabolic data on boswellic acids, this review presents different perspectives and gives a differentiated insight into the possible mechanisms of action of BSE in humans. It underlines BSE as a promising alternative to NSAIDs, which warrants investigation in further pharmacological studies and clinical trials.

ISOFLAVONI

British Journal of Nutrition (2005), 93, 731–739

Effect of consumption of soy isoflavones on behavioural, somatic and affective symptoms in women with premenstrual syndrome

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(Received 18 June 2004 – Revised 4 December 2004 – Accepted 13 December 2004)

Up to 80 % of the Western female population experience premenstrual syndrome (PMS). Long-term pharmacological therapy is unacceptable to most women, and is not warranted for moderate symptoms. Nutritional therapies are popular, but lack a clear evidence base. Anecdotal evidence suggests beneficial effects of soy isoflavones because of their influence on endogenous oestrogen and actions on specific tissues. The effect of isolated soya protein (ISP) containing 68 mg/d (aglycone equivalents) soy isoflavones (IF) on premenstrual symptom severity was studied in a seven-menstrual cycle, double-blind, placebo-controlled, crossover intervention study in twenty-three women with prospectively confirmed PMS aged 18–35 years and BMI 19–30 kg/m2.
ISP containing IF or milk protein placebo was consumed for two complete menstrual cycles. ISP containing IF (genistein, daidzein, equol) were measured in 24 h urine samples. After two cycles of ISP containing IF intervention, total symptoms (F(2,36) 8·20, P¼0·000) and physical symptoms (F(2,36) 8·18, P¼0·000) were significantly reduced compared with baseline after both active and placebo treatments, although differences between active and placebo treatment were non-significant.
Specific premenstrual symptoms, headache (F(2,32) 4·10, P¼0·026) and breast tenderness (F(2,32) 4·59, P¼0·018), were reduced from baseline after soy IF, but not milk protein placebo. Cramps (F(2,32) 4·15, P¼0·025) and swelling (F(2,32) 4·64, P¼0·017) were significantly lower after active treatment compared
with placebo. Concentrations of genistein and daidzein were increased following soy IF consumption, but equol production did not enhance symptom reduction.
The present study showed that ISP containing IF may have potential to reduce specific premenstrual symptoms via non-classical actions.

The Effects of Soy on the Menstrual Cycle

by LILLIAN DOWNEY Last Updated: Apr 23, 2015

Decreased Menstrual Pain

Dysmenorrhea is a medical condition that's marked by painful menstrual periods. It's caused by chemicals in the body called prostaglandins, which trigger your uterus to contract (cramp). In some women, this cramping and pain is severe enough to interfere with daily life. Some women who experience dysmenorrhea find relief when they eat less red meat and more soy products, according to the University of Maryland Medical Center.

Nursing and Health Sciences 8(2):108 - 113 · June 2006

Intake of dietary soy isoflavones in relation to perimenstrual symptoms of Korean women living in the USA

Abstract

Abstract This study was conducted to identify the potential relationship between the dietary intake level of soy isoflavones and perimenstrual symptomatology. The research design was a cross-sectional study. The sample was made up of 84 Korean women living in the USA, aged 28–40 years. The Moos Menstrual Distress Questionnaire (MDQ) and the Food Frequency Questionnaire were used as measurement tools. The soy isoflavone intake was significantly correlated with MDQ scores in the menstrual phase. In conclusion, the beneficial effect of dietary soy isoflavones on certain menstrual symptoms was established, suggesting that soy isoflavones could be one of the dietary factors related to the complexity of premenstrual syndrome (PMS). The positive effect of soy isoflavones on PMS warrants further study.

AGNOCASTO

Iran J Pharm Res. 2014 Summer; 13(3): 757–767.
PMCID: PMC4177637

Effect of Medicinal Herbs on Primary Dysmenorrhoea- a Systematic Review

Parvaneh Mirabi, Seideh Hanieh Alamolhoda, Seddigheh Esmaeilzadeh, and Faraz Mojab

Vitex agnus-castus

One of the herbal medicines used for treating menstrual disorders is an herbal drop called Vitagnous® and a combination which is derived from *V. agnus-cactus* plants. This plant has a dopaminergic effect. Important combinations of *V. agnus-castus*, especially its essential oil, affect hypothalamus-pituitary axis and decrease secretion of FSH, release of LH and increase progesterone. Indeed, physiological and pharmacological effects of this drug cause human body to naturally balance hormonal reduction or increase (52)

In one study, the effects of Vitagnous® were compared with those of placebo and it was reported that Vitagnous® was more effective than placebo in terms of reducing pain intensity (53).

Iran J Nurs Midwifery Res. 2014 Nov-Dec; 19(6): 581–584.
PMCID: PMC4280721

Comparative evaluation of the efficacy of herbal drugs (fennelin and vitagnus) and mefenamic acid in the treatment of primary dysmenorrhea

Fatemeh Zeraati, Fatemeh Shobeiri, Mansour Nazari, Malihe Araghchian, and Reza Bekhradi

This double-blind clinical trial was carried out in 105 students with mild and moderate dysmenorrhea. The students were randomly divided into four groups which received the extracts of fennelin and vitagnus, mefenamic acid, and placebo, respectively. Severity of pain was detected by the Visual Analog Scale (VAS) during one cycle before and two cycles after the intervention. Data were analyzed by SPSS version 16 and (P < 0.05 was considered significant.

Results:

Demographic characteristics of the students were similar in the four groups. There was no significant difference in the mean of severity of dysmenorrhea during one cycle before the intervention between the four groups, but the difference was significant during two cycles after the intervention. Fennelin had similar effects as vitagnus on dysmenorrhea. Mefenamic acid had less effect than both the drugs (P <0.05).

Conclusion:

Fennelin and vitagnus had higher effect than mefenamic acid. Use of these products is suggested for dysmenorrhea.

Med Monatsschr Pharm. 2009 May;32(5):186-91.
[The premenstrual syndrome: effectiveness of Vitex agnus castus].
Döll M.
Abstract
Premenstrual syndrome (PMS) is a complex combination of a variety of symptoms including mood swings, anxiety, depression, tender breasts and food cravings. For some women the physical pain and emotional stress are severe enough to affect their daily routines and activities. The causes of the premenstrual syndrome have not yet been understood clearly, but have been attributed to hormonal and neuronal dysbalance, diet and lifestyle. Hyperprolactinemia seems to be an important factor which is considered to be part of the endocrine disorder. Different clinical investigations and double blind trials have shown that preparations containing Vitex agnus castus fruit extract are a useful tool to decrease pathophysiologicaly increased prolactin serum levels and though could be an effective treatment for women suffering from premenstrual syndrome.

Aust N Z J Obstet Gynaecol. 2010 Apr;50(2):189-93. doi: 10.1111/j.1479-828X.2010.01137.x.

Evaluating therapeutic effect in symptoms of moderate-to-severe premenstrual syndrome with Vitex agnus castus (BNO 1095) in Chinese women.

Ma L, Lin S, Chen R, Zhang Y, Chen F, Wang X.

Abstract

OBJECTIVES:

To assess therapeutic effect of an extract of Vitex agnus castus (VAC, BNO 1095) in premenstrual syndrome (PMS) in Chinese women.

DESIGN:

It was a prospective, randomised, double-blind, placebo-controlled study carried out in China. Eligible patients were treated with VAC extract or placebo for three cycles. Symptoms were documented with PMS diary (PMSD), a daily rating scale with 17 items. Main efficacy variable was the reduction percentage of 17 symptom score documented in PMSD during the luteal phase of the third treatment cycle.

RESULTS:

A total of 67 patients were enrolled and randomly assigned to VAC group or placebo group. Of these, 64 patients completed the study (31 vs. 33). All the 17 symptoms showed a significantly greater improvement with VAC than placebo ($P < 0.05$) except lower abdominal cramping ($P > 0.05$).

CONCLUSION:

Vitex agnus castus is more effective than placebo in the treatment of moderate-to-severe PMS in Chinese women, especially in symptoms of negative effect and insomnia.

BMJ. 2001 Jan 20; 322(7279): 134–137.
PMCID: PMC26589

Treatment for the premenstrual syndrome with agnus castus fruit extract: prospective, randomised, placebo controlled study

R Schellenberg, senior consultant for the study group

Abstract

Objectives

To compare the efficacy and tolerability of agnus castus fruit (*Vitex agnus castus* L extract Ze 440) with placebo for women with the premenstrual syndrome.

Design

Randomised, double blind, placebo controlled, parallel group comparison over three menstrual cycles.

Setting

General medicine community clinics.

Participants

178 women were screened and 170 were evaluated (active 86; placebo 84). Mean age was 36 years, mean cycle length was 28 days, mean duration of menses was 4.5 days.

Interventions

Agnus castus (dry extract tablets) one tablet daily or matching placebo, given for three consecutive cycles.

Main outcome measures

Main efficacy variable: change from baseline to end point (end of third cycle) in women's self assessment of irritability, mood alteration, anger, headache, breast fullness, and other menstrual symptoms including bloating. Secondary efficacy variables: changes in clinical global impression (severity of condition, global improvement, and risk or benefit) and responder rate (50% reduction in symptoms).

Results

Improvement in the main variable was greater in the active group compared with placebo group ($P<0.001$). Analysis of the secondary variables showed significant ($P<0.001$) superiority of active treatment in each of the three global impression items. Responder rates were 52% and 24% for active and placebo, respectively. Seven women reported mild adverse events (four active; three placebo), none of which caused discontinuation of treatment.

Conclusions

Dry extract of agnus castus fruit is an effective and well tolerated treatment for the relief of symptoms of the premenstrual syndrome.

Pol Merkur Lekarski. 2015 Jul;39(229):43-6.

[Vitex Agnus Castus in the treatment of hyperprolactinemia and menstrual disorders - a case report].

Męczekalski B, Czyżyk A.

Abstract

We describe a patient with mild hyperprolactinemia and menstrual disorders (oligomenorrhea). She presented relative hypoestrogenism in laboratory tests. Magnetic resonans excluded the presence of pituitary adenoma. Because patient developed a bromocriptine intolerance, the Vitex Agnus Castus (VAC) extract has been introduced. The VAC therapy was effective, with symptoms relief and improvement of hormonal tests. The VAC medicines are indicated for the treatment of premenstrual syndrome (PMS), mastalgia, menstrual disorders and mild hyperprolactinemia. The mechanism of action is not fully understood, but it is related to dopaniergic activity of diterpenes and castacin in VAC. The randomized clinical trials revealed efficacy of VAC extract in the treatmet of hyperprolactinemia, menstrual disorders, PMS and mastalgia. Good tolerability, lack of serious side-effects and drug interactions are the advantages of the VAC preparations.

Electron Physician. 2017 Jan 25;9(1):3685-3689. doi: 10.19082/3685. eCollection 2017.

Systematic Review of Premenstrual, Postmenstrual and Infertility Disorders of Vitex Agnus Castus.

Rafieian-Kopaei M, Movahedi M.

Abstract

INTRODUCTION:

Vitex agnus-castus, also called vitex is aboriginal to the Mediterranean region, with long leaves, tender stem, flowers and ripening seeds. The aim of this study was to overview premenstrual, postmenstrual and infertility disorder of Vitex agnus-castus.

METHODS:

This review article was carried out by searching studies in PubMed, Medline, Web of Science, and IranMedex databases. The initial search strategy identified about 87 references. In this study, 43 studies were accepted for further screening, and met all our inclusion criteria (in English, full text, therapeutic effects of Vitex agnus-castus and dated mainly from the year 2009 to 2016). The search terms were Vitex agnus-castus, premenstrual, postmenstrual, infertility disorder properties and pharmacological effects.

RESULT:

Vitex agnus-castus was shown to contribute to the treatment of premenstrual syndrome (PMS). Moreover, the result of the present study showed that this valuable plant is helpful in alleviation of pain resulting from postmenstrual disease. Furthermore, it was found that Vitex agnus-castus is beneficial in infertility disorder.

CONCLUSION:

Vitex agnus-castus (AC) is a phytopharmaceutical compound and is shown to be widely used to treat PMS and PMDD. In addition, it was shown to be beneficial in post-menstrual cases and it can also contribute to treatment of infertility cases in both men and women. Dopaminergic compounds available in this plant help to treat premenstrual mastodynia as well as other symptoms of the premenstrual syndrome.

VITAMINA B6

J Caring Sci. 2012 Nov 22;1(4):183-9. doi: 10.5681/jcs.2012.026. eCollection 2012.

Effects of magnesium and vitamin b6 on the severity of premenstrual syndrome symptoms.

Ebrahimi E, Khayati Motlagh S, Nemati S, Tavakoli Z.

Abstract

INTRODUCTION:

The importance of resolving the problem of premenstrual syndrome for patients has been emphasized due to its direct and indirect economical effects on the society. The aim of the current study was to evaluate the effects of magnesium and vitamin B6 on the severity of premenstrual syndrome in patients referring to health centers affiliated to Isfahan University of Medical Sciences, Iran, during 2009-10.

METHODS:

This two-stage double-blind clinical trial was conducted on 126 women who were randomly allocated into 3 groups to receive magnesium, vitamin B6, or placebo. The study was performed in 10 selected health centers in Isfahan and lasted for 4 months. To confirm premenstrual syndrome, the participants were asked to complete a menstrual diary for 2 months at home. Drug interventions were continued for two cycles and the results of before and after the intervention were compared.

RESULTS:

The findings of this study showed that the mean scores of premenstrual syndrome significantly decreased after the intervention in all groups ($p < 0.05$).

CONCLUSION:

According to our findings, vitamin B6 and placebo had the most and least efficiency in improving the mean premenstrual syndrome score.

Psychother Psychosom. 2004 Nov-Dec;73(6):340-3.
Vitamin B6 level is associated with symptoms of depression.
Hvas AM, Juul S, Bech P, Nexø E.
Abstract
BACKGROUND:
A low level of vitamin B6 might theoretically cause depression as vitamin B6 is a cofactor in the tryptophan-serotonin pathway. In the present study, we examined the association between depression and the phosphate derivative of vitamin B6 in plasma, pyridoxal phosphate (PLP).
METHODS:
In 140 individuals, symptoms of depression were evaluated by the Major Depression Inventory, and biochemical markers of vitamin B deficiency were measured.
RESULTS:
We found that 18 (13%) individuals were depressed. A low plasma level of PLP was significantly associated with the depression score (p=0.002). No significant association was found between depression and plasma vitamin B12 (p=0.13), plasma methylmalonic acid (p=0.67), erythrocyte folate (p=0.77), and plasma total homocysteine (p=0.16).
CONCLUSION:
Our study suggests that a low level of plasma PLP is associated with symptoms of depression. Randomized trials are now justified and needed in order to examine whether treatment with vitamin B6 may improve symptoms of depression.