GENISTEINA

Am J Clin Nutr. 2014 Jul;100 Suppl 1:423S-30S. doi: 10.3945/ajcn.113.071464.
Soy foods, isoflavones, and the health of postmenopausal women.
Messina M.
Abstract
Over the past 2 decades, soy foods have been the subject of a vast amount of research, primarily because they are uniquely rich sources of isoflavones. Isoflavones are classified as both phytoestrogens and selective estrogen receptor modulators. The phytoestrogenic effects of isoflavones have led some to view soy foods and isoflavone supplements as alternatives to conventional hormone therapy. However, clinical research shows that isoflavones and estrogen exert differing effects on a variety of health outcomes. Nevertheless, there is substantial evidence that soy foods have the potential to address several conditions and diseases associated with the menopausal transition. For example, data suggest that soy foods can potentially reduce ischemic heart disease through multiple mechanisms. Soy protein directly lowers blood low-density lipoprotein-cholesterol concentrations, and the soybean is low in saturated fat and a source of both essential fatty acids, the omega-6 fatty acid linoleic acid and the omega-3 fatty acid alpha-linolenic acid. In addition, soflavones improve endothelial function and possibly slow the progression of subclinical atherosclerosis. Isoflavone supplements also consistently alleviate menopausal hot flashes provided they contain sufficient amounts of the predominant soybean isoflavone genistein. In contrast, the evidence that isoflavones reduce bone loss in postmenopausal women is unimpressive. Whether adult soy food intake reduces breast cancer risk is unclear. Considerable evidence suggests that for soy to reduce risk, consumption during childhood and/or adolescence is required. Although concerns have been raised that soy food consumption may be harmful to breast cancer patients, an analysis in 9514 breast cancer survivors who were followed for 7.4 y found that higher postdiagnosis soy intake was associated with a significant 25% reduction in tumor recurrence. In summary, the clinical and epidemiologic data indicate that adding soy foods to the diet can contribute to the health of postmenopausal women.

Menopause. 2012 Jul;19(7):791-8. doi: 10.1097/gme.0b013e31823dbeda.

Soy germ isoflavones improve menopausal symptoms but have no effect on blood lipids in early postmenopausal Chinese women: a randomized placebo-controlled trial.

Ye YB, Wang ZL, Zhuo SY, Lu W, Liao HF, Verbruggen M, Fang S, Mai HY, Chen YM, Su YX.

Abstract

OBJECTIVE:

Estrogen therapy is, to date, the most effective treatment of menopausal syndrome and also has a favorable effect on lipid profiles. Because of its potential adverse effects, however, a more acceptable alternative therapy needs to be identified. This study examines the effect of soy germ isoflavones on menopausal symptoms and serum lipids.

METHODS:

Ninety early postmenopausal Chinese women, aged 45 to 60 years, were randomly assigned to three treatment groups (30 each) receiving daily doses of 0 (placebo), 84, and 126 mg of soy germ isoflavones. Hot flush frequency, Kupperman scores, serum 17β-estradiol, follicle-stimulating hormone, luteinizing hormone, and serum lipids, including triglyceride, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, apolipoprotein A-I, and apolipoprotein B100, were assessed at baseline and at 12 and 24 weeks after treatment.

RESULTS:

Both the frequency of hot flushes and the Kupperman index score decreased in all three treatment groups during the intervention period, but the percentage decreases in both were significantly greater in the two isoflavone groups (44.3 ± 19.1 and 57.8 ± 37.4 [84 mg isoflavones]; 48.5 ± 27.2 and 56.7 ± 26.7 [126 mg isoflavones]) than in the placebo group (27.8 ± 15.5 and 34.6 ± 46.2; $p < 0.01$). There was no significant difference in the changes in estradiol, follicle-stimulating hormone, and luteinizing hormone among the three treatment groups during the study, and no significant differences were observed in the lipid components.

CONCLUSIONS:

A daily supplement of 84 or 126 mg soy germ isoflavones may improve menopausal symptoms, although neither dose was found to affect lipid profiles in early postmenopausal Chinese women after 24 weeks of treatment. The favorable effects are unlikely to be associated with female hormones.

Climacteric. 2016 Oct 6:1-11.

Effects of phytoestrogens on bone mineral density during the menopause transition: a systematic review of randomized, controlled trials.

Abdi F, Alimoradi Z, Haqi P, Mahdizad F.

Abstract

INTRODUCTION:

Menopause is associated with increased bone resorption and decreased bone mineral density (BMD). Phytoestrogens are believed to prevent bone loss. This study reviewed relevant randomized, controlled trials to determine the effects of phytoestrogens on BMD in postmenopausal women.

METHODS:

In order to perform this systematic review, PubMed, Science Direct, Scopus, Cochrane Library, ISI Web of Knowledge, and ProQuest databases were searched for articles published during 2005-2016. The main keywords used during the searches were "phytoestrogen" and "bone mineral density" and "menopause". The Cochrane Risk of Bias Assessment Tool was used to evaluate the quality of the selected studies and to assess the risk of bias.

RESULTS:

A total of 23 eligible studies were included in this systematic review. Most selected studies used a double-blind, placebo-controlled design. In total, 3494 participants were enrolled in the selected trials. Different types of soy isoflavone extracts, including genistein extracts (either alone or in combination with daidzein), dietary products containing different amounts of phytoestrogens, and red clover extracts were used in the designed interventions. The duration of the interventions ranged from 7 weeks to 3 years. In most studies, the primary outcome was the efficacy of the designed intervention which was assessed through measuring whole body or regional BMD or bone mineral content, T-scores, and biomarkers of bone metabolism.

CONCLUSIONS:

Isoflavones probably have beneficial effects on bone health in menopausal women. Nevertheless, there were controversial reports about changes in BMD. Supplementation with a phytoestrogen can probably prevent the reduction in BMD and maintain a healthy bone structure during menopause.

Endocrine. 2016 Apr 28.

Visfatin correlates with hot flashes in postmenopausal women with metabolic syndrome: effects of genistein.

Bitto A, Arcoraci V, Alibrandi A, D'Anna R, Corrado F, Atteritano M, Minutoli L, Altavilla D, Squadrito F.

Abstract

During menopause, an increased prevalence of metabolic syndrome (MetS) and central obesity seems to increase hot flashes (HFs). Visfatin is an inflammatory adipokine secreted by visceral fat. We investigated visfatin levels and its relationship with hot flash number and BMI, in postmenopausal women with MetS. We also evaluated the effect of genistein, an isoflavone effective in reducing HFs, on visfatin levels and HFs after 1 year of treatment. This was a randomized, double-blind, placebo-controlled trial. Postmenopausal women with MetS were randomly assigned to receive placebo (n = 60) or 54 mg genistein (n = 60), daily for 1 year. As main outcome measures, hot flashes number and circulating visfatin levels were evaluated. Visfatin significantly correlated with BMI and HFs number in women with MetS at basal. After 6 and 12 months, our results indicate a strong correlation and a significant effect of genistein in reducing both HFs and visfatin in women with MetS. The present study suggests that visfatin plays a role in the vasomotor symptoms, at least in postmenopausal women with metabolic syndrome. Genistein may reduce HFs decreasing the circulating levels of this inflammatory adipokine.

Osteoporos Int. 2014 Mar;25(3):1123-9. doi: 10.1007/s00198-013-2512-5.

Genistein effects on quality of life and depression symptoms in osteopenic postmenopausal women: a 2-year randomized, double-blind, controlled study.

Atteritano M, Mazzaferro S, Bitto A, Cannata ML, D'Anna R, Squadrito F, Macrì I, Frisina A, Frisina N, Bagnato G.

Abstract

SUMMARY:

Postmenopausal estrogen decline is implicated in several age-related physical and psychological changes in women, including decreases in perceived quality of life. The phytoestrogen genistein at a dose of 54 mg daily in osteopenic postmenopausal women after 2 years implies an improvement on quality of life and depression symptoms.

INTRODUCTION:

Postmenopausal estrogen decline is implicated in several age-related physical and psychological changes in women, including decreases in perceived quality of life (QoL). A number of trials with hormone therapy showed beneficial effects of the intervention on quality of life parameters. However, because of known or suspected serious side effects of conventional hormone therapy, there is a need for alternatives.

METHODS:

We conducted a double-blind randomized placebo-controlled trial using the isoflavone genistein, 54 mg, or placebo for 2 years. In this trial, we recruited 262 postmenopausal women aged 49 to 67 years.

RESULTS:

At baseline, after 1 year, and at final visit, participants filled in the Short Form of 36 questions (SF-36) and the Zung Self-rating Depression Scale (ZSDS). For the placebo group, scores on all dimensions of the SF-36 decreased after 1 and 2 years. The genistein group showed increases on all dimensions of the SF-36 at the end of the study. There were, however, statistically significant differences in changes of scores between the two intervention groups. For the ZSDS, similarly, significant differences were found between groups.

CONCLUSION:

In conclusion, the findings of this randomized trial showed that genistein improves quality of life (health status, life satisfaction, and depression) in osteopenic postmenopausal women.

J Bone Miner Res. 2013 Apr;28(4):780-93. doi: 10.1002/jbmr.1815.

Effect of exercise training combined with isoflavone supplementation on bone and lipids in postmenopausal women: a randomized clinical trial.

Chilibeck PD, Vatanparast H, Pierson R, Case A, Olatunbosun O, Whiting SJ, Beck TJ, Pahwa P, Biem HJ.

Abstract

We determined the effects of 2 years of exercise training and soy isoflavone supplementation on bone mass and lipids in postmenopausal women provided with calcium and vitamin D. Women were randomized to four groups: exercise training (Ex); isoflavone supplementation (Iso: 165 mg/d [105 mg/d aglycone equivalent]); combined Ex and Iso (ExIso); and placebo (control). Exercise included resistance training (2 days/week) and walking (4 days/week). Our primary outcomes were lumbar spine and hip bone mineral density (BMD). Secondary outcomes included hip geometry, tibia and radius speed of sound (SOS), dynamic balance (6 m backward tandem walking), blood lipids, mammography, and endometrial thickness. A total of 351 women (Ex = 86, Iso = 90, ExIso = 87, control = 88) were randomized, with 298 analyzed at 2 years (Ex = 77, Iso = 76, ExIso = 72, control = 73). There was a significant interaction for total hip BMD ($p < 0.001$) such that ExIso had a greater rate of decrease (absolute change [95% confidence interval] = -0.018 [-0.024, -0.012] g/cm(2)) than either the Ex or Iso groups alone (-0.005 [-0.01, 0.001] and -0.005 [-0.011, 0.001] g/cm(2) , respectively). There were no differences between groups for changes in lumbar spine BMD and minimal significant changes in hip geometric properties and bone SOS. Exercise groups improved dynamic balance as measured by a decrease in backward tandem walking time over 6 m ($p = 0.017$). Isoflavone groups decreased low density lipoproteins (Iso: -0.20 [-0.37, -0.02] mmol/L; ExIso: -0.23 [-0.40, -0.06] mmol/L; $p = 0.003$) compared to non-isoflavone groups (Ex: 0.01 [-0.16, 0.18] mmol/L; control: -0.09 [-0.27, 0.08] mmol/L) and had lower adverse reports of menopausal symptoms (14% versus 33%; $p = 0.01$) compared to non-isoflavone groups. Isoflavone supplementation did not increase endometrial thickness or abnormal mammograms. We conclude exercise training and isoflavone supplementation maintain hip BMD compared to control, but these two interventions interfere with each other when combined. Isoflavone supplementation decreased LDL and adverse events related to menopausal symptoms.

Menopause. 2010 Sep-Oct;17(5):1080-6. doi: 10.1097/gme.0b013e3181dd05a9.

Effects of soy isoflavones and genistein on glucose metabolism in perimenopausal and postmenopausal non-Asian women: a meta-analysis of randomized controlled trials.

Ricci E, Cipriani S, Chiaffarino F, Malvezzi M, Parazzini F.

Abstract

OBJECTIVE:

Several randomized controlled trials (RCTs) have examined the role of soy isoflavones on cardiovascular risk factors in perimenopausal and postmenopausal women and have yielded inconsistent results. This meta-analysis aimed to assess the overall effect of soy isoflavones on glucose metabolism: fasting blood glucose, insulin, and insulin resistance.

METHODS:

We searched for all articles published in English and indexed in Medline from January 1990 to December 2009. We included RCTs for soy isoflavone supplementation in perimenopausal and postmenopausal women not taking hormone therapy, selecting non-Asian women only. The main outcomes were fasting blood glucose changes from baseline.

RESULTS:

We identified 10 eligible RCTs containing blood glucose data of 794 women. The main result was that soy isoflavones did not affect fasting blood glucose significantly. Under a random-effects model, the average difference in fasting blood glucose values between women assigned to isoflavones and women assigned to placebo was -2.16 mg/dL (95% CI, -5.21 to 0.89 mg/dL; P = 0.17). In genistein studies, the mean difference was -7.15 mg/dL (95% CI, -11.47 to -2.82). However, the effects on insulin and homeostasis model assessment insulin resistance were significant: -1.37 microIU/mL (95% CI, -1.92 to -0.81 microIU/mL) and -0.39 (95% CI, -0.65 to -0.14), respectively. Subgroup analyses did not show a significant effect of isoflavone dose, whereas isoflavone mixtures and genistein had a different effect on fasting blood glucose.

CONCLUSIONS:

This meta-analysis of RCTs showed that isoflavone use was not associated with a significant glycemia reduction in perimenopausal and postmenopausal non-Asian women. However, the few studies that reported insulin and homeostasis model assessment insulin resistance changes suggested that soy isoflavones and genistein alone had a beneficial effect on glucose metabolism.

Maturitas. 2011 Feb;68(2):189-96. doi: 10.1016/j.maturitas.2010.11.012.

The effect of synthetic genistein on menopause symptom management in healthy postmenopausal women: a multi-center, randomized, placebo-controlled study.

Evans M, Elliott JG, Sharma P, Berman R, Guthrie N.

Abstract

OBJECTIVE:

To evaluate the efficacy of synthetic genistein for reducing the frequency and severity of hot flushes.

STUDY DESIGN:

A 12 week randomized double-blind, placebo-controlled study in which 84 postmenopausal women received placebo or a single 30 mg dose of synthetic genistein. Outcome measures primary: percentage change in the number of daily hot flushes from pre-treatment to week 12. Secondary: duration and severity of daily hot flushes, Greene Climacteric Scale score, serum follicle stimulating hormone (FSH), 17β-estradiol and endometrial thickness.

RESULTS:

Genistein supplemented subjects completing at least 4 weeks on trial (n=40) demonstrated a 51% reduction (9.4-4.7/day) in the number of hot flushes by week 12 compared to a 27% reduction in the placebo group (9.9-7.1/day) (p=0.026). Subjects in the genistein group also reported significantly fewer hot flushes per day (p=0.010) and a decrease in total duration of hot flushes per day (p=0.009) at week 12 versus placebo. Subjects on genistein (n=32) completing 12 weeks on trial demonstrated a 51% reduction (9.7-4.7/day) in the number of hot flushes by week 12 (p=0.049) compared to 30% reduction in the placebo group (9.8-7.0/day) and had fewer hot flushes per day and a decrease in total duration of hot flushes per day at week 12 compared to placebo (p=0.020 and p=0.017, respectively). There were no differences between groups in Greene Climacteric Scale, FSH, 17β-estradiol, endometrial thickness or adverse events.

CONCLUSIONS:

The current study provides the first evidence that a single daily dose of 30 mg of synthetic genistein reduces hot flush frequency and duration.

Menopause. 2005 Mar;12(2):186-92.

Effects of the phytoestrogen genistein on cardiovascular risk factors in postmenopausal women.

Crisafulli A, Altavilla D, Marini H, Bitto A, Cucinotta D, Frisina N, Corrado F, D'Anna R, Squadrito G, Adamo EB, Marini R, Romeo A, Cancellieri F, Buemi M, Squadrito F.

Abstract

OBJECTIVE:

The phytoestrogen genistein has been shown to be the most efficacious in clinical and experimental studies. We studied whether genistein treatment affects some cardiovascular risk markers in postmenopausal women.

DESIGN:

Sixty healthy postmenopausal women, who were 52 to 60 years of age, were enrolled in a 6-month double-blind, placebo-controlled, randomized study. After a 4-week stabilization on a standard fat-reduced diet, participants were randomly assigned to receive either genistein (n = 30; 54 mg/d) or placebo (n = 30). At baseline and after a 6-month treatment, we measured fasting glucose, insulin, insulin resistance (HOMA-IR), osteoprotegerin (OPG), fibrinogen, and sex hormone-binding globulin (SHBG).

RESULTS:

By comparison with placebo, genistein treatment decreased significantly fasting glucose (genistein = -8.7 +/- 2.3%; placebo = 3.2 +/- 2.3%; P < 0.001), fasting insulin (genistein = -12 +/- 3.33%; placebo = 36 +/- 3.29%; P < 0.001), and HOMA-IR (genistein = -14 +/- 5.8%; placebo = 42 +/- 0.6%; P < 0.001). After genistein-treatment, fibrinogen decreased (genistein = 3.18 +/- 0.12 g/L; placebo = 3.83 +/- 0.04 g/L; P < 0.001) with respect to placebo. In the genistein group, serum OPG was lower (-2 +/- 0.3%) than in placebo (9 +/- 1.5%; P < 0.001), and serum SHBG was higher (63 +/- 3.8 nmol/L) compared with placebo (53 +/- 2.9 nmol/L; P < 0.05).

CONCLUSION:

Our study suggests that genistein may have a favorable effect on some cardiovascular markers.

Menopause. 2004 Jul-Aug

Effects of genistein on hot flushes in early postmenopausal women: a randomized, double-blind EPT- and placebo-controlled study.

Crisafulli A, Marini H, Bitto A, Altavilla D, Squadrito G, Romeo A, Adamo EB, Marini R, D'Anna R, Corrado F, Bartolone S, Frisina N, Squadrito F.

Abstract

OBJECTIVE:

We evaluated and compared the effects of the phytoestrogen genistein, estrogen-progestogen therapy (EPT), and placebo on hot flushes and endometrial thickness in postmenopausal women.

DESIGN:

Ninety healthy, postmenopausal women, 47 to 57 years of age, were randomly assigned to receive for 1 year continuous EPT (n = 30; 1 mg 17beta-estradiol combined with 0.5 mg norethisterone acetate), the phytoestrogen genistein (n = 30; 54 mg/day), or placebo (n = 30). Endometrial safety was evaluated by intravaginal ultrasounds at baseline, 6 and 12 months.

RESULTS:

By comparison with placebo, daily flushes reduced significantly by a mean of 22% (95% CI: -38 to -6.2; P < 0.01) after 3 months, by a mean of 29% (95% CI: -45 to -13; P < 0.001) after 6 months, and by a mean of 24% (95% CI: -43 to -5; P < 0.01) after 12 months of genistein treatment. Flush score decreased by a mean of 53% (95% CI: -79 to -26; P < 0.001) after 3 months, by a mean of 56% (95% CI: -83 to -28; P < 0.001) after 6 months, and by a mean of 54% (95% CI: -74 to -33; P < 0.001) after 12 months of EPT, as compared with placebo. No side effect was observed on the uterus of the participants.

CONCLUSIONS:

The present study confirms that genistein might have positive effects on hot flushes without a negative impact on endometrial thickness and suggests a future role of this phytoestrogen as a strategically therapeutic alternative in the management of postmenopausal symptoms.

Ann Intern Med. 2007 Jun 19;146(12):839-47.

Effects of the phytoestrogen genistein on bone metabolism in osteopenic postmenopausal women: a randomized trial.

Marini H, Minutoli L, Polito F, Bitto A, Altavilla D, Atteritano M, Gaudio A, Mazzaferro S, Frisina A, Frisina N, Lubrano C, Bonaiuto M, D'Anna R, Cannata ML, Corrado F, Adamo EB, Wilson S, Squadrito F.

Abstract

BACKGROUND:

Observational studies and small trials of short duration suggest that the isoflavone phytoestrogen genistein reduces bone loss, but the evidence is not definitive.

OBJECTIVE:

To assess the effects of genistein on bone metabolism in osteopenic postmenopausal women.

DESIGN:

Randomized, double-blind, placebo-controlled trial.

SETTING:

3 university medical centers in Italy.

PATIENTS:

389 postmenopausal women with a bone mineral density (BMD) less than 0.795 g/cm2 at the femoral neck and no significant comorbid conditions.

INTERVENTION:

After a 4-week stabilization period during which participants received a low-soy, reduced-fat diet, participants were randomly assigned to receive placebo (n = 191) or 54 mg of genistein (n = 198) daily for 24 months. Both the genistein and placebo tablets contained calcium and vitamin D.

MEASUREMENTS:

The primary outcome was BMD at the anteroposterior lumbar spine and femoral neck at 24 months. Secondary outcomes were serum levels of bone-specific alkaline phosphatase and insulin-like growth factor I, urinary excretion of pyridinoline and deoxypyridinoline, and endometrial thickness. Data on adverse events were also collected.

RESULTS:

At 24 months, BMD had increased in genistein recipients and decreased in placebo recipients at the anteroposterior lumbar spine (change, 0.049 g/cm2 [95% CI, 0.035 to 0.059] vs. -0.053 g/cm2 [CI, -0.058 to -0.035]; difference, 0.10 g/cm2 [CI, 0.08 to 0.12]; P < 0.001) and the femoral neck (change, 0.035 g/cm2 [CI, 0.025 to 0.042] vs. -0.037 g/cm2 [CI, -0.044 to -0.027]; difference, 0.062 g/cm2 [CI, 0.049 to 0.073]; P < 0.001). Genistein statistically significantly decreased urinary excretion of pyridinoline and deoxypyridinoline, increased levels of bone-specific alkaline phosphatase and insulin-like growth factor I, and did not change endometrial thickness compared with placebo. More genistein recipients than placebo recipients experienced gastrointestinal side effects (19% vs. 8%; P = 0.002) and discontinued the study.

LIMITATIONS:

The study did not measure fractures and had limited power to evaluate adverse effects.

CONCLUSION:

Twenty-four months of treatment with genistein has positive effects on BMD in osteopenic postmenopausal women.

CIMICIFUGA

Springerplus. 2015 Feb 10;4:65. doi: 10.1186/s40064-015-0808-y. eCollection 2015.

A systematic review of non-hormonal treatments of vasomotor symptoms in climacteric and cancer patients.

Drewe J, Bucher KA, Zahner C.

Abstract

The cardinal climacteric symptoms of hot flushes and night sweats affect 24-93% of all women during the physiological transition from reproductive to post-reproductive life. Though efficacious, hormonal therapy and partial oestrogenic compounds are linked to a significant increase in breast cancer. Non-hormonal treatments are thus greatly appreciated. This systematic review of published hormonal and non-hormonal treatments for climacteric, and breast and prostate cancer-associated hot flushes, examines clinical efficacy and therapy-related cancer risk modulation. A PubMed search included literature up to June 19, 2014 without limits for initial dates or language, with the search terms, (hot flush* OR hot flash*) AND (clinical trial* OR clinical stud*) AND (randomi* OR observational) NOT review). Retrieved references identified further papers. The focus was on hot flushes; other symptoms (night sweats, irritability, etc.) were not specifically screened. Included were some 610 clinical studies where a measured effect of the intervention, intensity and severity were documented, and where patients received treatment of pharmaceutical quality. Only 147 of these references described studies with alternative non-hormonal treatments in post-menopausal women and in breast and prostate cancer survivors; these results are presented in Additional file 1. The most effective hot flush treatment is oestrogenic hormones, or a combination of oestrogen and progestins, though benefits are partially outweighed by a significantly increased risk for breast cancer development. This review illustrates that certain non-hormonal treatments, including selective serotonin reuptake inhibitors, gabapentin/pregabalin, and Cimicifuga racemosa extracts, show a positive risk-benefit ratio. Key points. Several non-hormonal alternatives to hormonal therapy have been established and registered for the treatment of vasomotor climacteric symptoms in peri- and post-menopausal women.There are indications that non-hormonal treatments are useful alternatives in patients with a history of breast and prostate cancer. However, confirmation by larger clinical trials is required.

Chin Med. 2013 Nov 1;8(1):20. doi: 10.1186/1749-8546-8-20.

Efficacy of black cohosh (Cimicifuga racemosa L.) in treating early symptoms of menopause: a randomized clinical trial.

Mohammad-Alizadeh-Charandabi S, Shahnazi M, Nahaee J, Bayatipayan S.

Abstract

BACKGROUND:

This study aims to evaluate the efficacy of Black cohosh (Cimicifuga racemosa L.) in treating early menopausal symptoms.

METHODS:

This randomized, double-blind, placebo-controlled clinical trial was conducted on 84 early post-menopausal participants with Greene climacteric scale (GCS) scores of 15 to 42, who were referred to two public health care centers in Tehran, Iran, in 2011-2012. The participants were randomly allocated into treatment (6.5 mg of dried extract of Black cohosh roots daily) and control (placebo) groups with a ratio of 1:1. The participants took one tablet per day for 8 weeks. The GCS scores were recorded at baseline, and after 4 and 8 weeks of treatment. Data analysis was carried out using a general linear model with repeated measures with SPSS software. The level of significance was set at $P < 0.05$.

RESULTS:

There was no loss to follow-up during the 8 weeks of treatment. The GCS total score (primary outcome) in the treatment group was significantly lower than that in the control group at both week 4 [adjusted mean difference: -7.8 (95% confidence interval: -11.1 to -4.4)] and week 8 [-12.9 (-16.2 to -9.3)]. The treatment group showed significantly more improvement than the control group in all GCS subscale scores (vasomotor, psychiatric, physical, and sexual symptoms; secondary outcomes). The differences between the treatment and control groups at week 8 were significantly higher ($P < 0.001$) than those at week 4 in terms of the total scores and the vasomotor and psychiatric subscale scores. No side effects were reported.

CONCLUSIONS:

Black cohosh reduced the GCS total score and all GCS subscale scores (vasomotor, psychiatric, physical, and sexual symptoms) during 4 and 8 weeks of treatment.

CLINICAL TRIAL REGISTRATION:

This study was approved (Code 9061) by the Ethics Committee of Tabriz University of Medical Sciences and registered at the Iranian Registry of Clinical Trials with IRCT201107186709N4 on 15 January 2012.

J Caring Sci. 2013 Jun 1;2(2):105-13. doi: 10.5681/jcs.2013.013. eCollection 2013.

Effect of black cohosh (cimicifuga racemosa) on vasomotor symptoms in postmenopausal women: a randomized clinical trial.

Shahnazi M, Nahaee J, Mohammad-Alizadeh-Charandabi S, Bayatipayan S.

Abstract

INTRODUCTION:

Hot flash is considered to be an early and common symptom of menopause. The present study aimed to determine the impact of black cohosh (Cimicifuga racemosa) on vasomotor symptoms in postmenopausal women.

METHODS:

This was a randomized, double-blind, placebo-controlled clinical trial. This study was performed on 84 postmenopausal women. The participants were randomly divided into control and intervention groups. The participants of the intervention group received one black cohosh tablet per day and the control group received one placebo tablet per day for eight weeks. The severity of vasomotor symptoms and number of hot flashes were recorded during the pre-intervention phase, and 4 and 8 weeks after the intervention. The data were analyzed using repeated measures ANOVA and ANCOVA tests. The level of significance was considered lower than 0.05.

RESULTS:

There was a significant difference between the two groups in terms of severity and number of hot flashes in weeks 4 and 8 by controlling the intensity of vasomotor symptoms and number of hot flashes before the intervention. Moreover, using repeated measures ANOVA, the intergroup comparison indicated a significant difference in bothgroups (the test and control groups) in terms of severity of vasomotor symptoms and number of hot flashes.

CONCLUSION:

According to the findings of the study, it seems that black cohosh can be used as an effective alternative medicine in relieving menopausal vasomotor symptoms.

Gynecol Endocrinol. 2011 Oct;27(10):844-8. doi: 10.3109/09513590.2010.538097. Epub 2011 Jan 13.

Black cohosh (Cimicifuga racemosa) in tamoxifen-treated breast cancer patients with climacteric complaints - a prospective observational study.

Rostock M, Fischer J, Mumm A, Stammwitz U, Saller R, Bartsch HH.

Abstract

OBJECTIVE:

The antihormonal therapy of breast cancer patients with the antiestrogen tamoxifen often induces or aggravates menopausal complaints. As estrogen substitution is contraindicated, herbal alternatives, e.g. extracts of black cohosh are often used.

DESIGN:

A prospective observational study was carried out in 50 breast cancer patients with tamoxifen treatment. All patients had had surgery, most of them had undergone radiation therapy (87%) and approximately 50% had received chemotherapy. Every patient was treated with an isopropanolic extract of black cohosh (1-4 tablets, 2.5 mg) for 6 months. Patients recorded their complaints before therapy and after 1, 3, and 6 months of therapy using the menopause rating scale (MRS II).

RESULTS:

The reduction of the total MRS II score under black cohosh treatment from 17.6 to 13.6 was statistically significant. Hot flashes, sweating, sleep problems, and anxiety improved, whereas urogenital and musculoskeletal complaints did not change. In all, 22 patients reported adverse events, none of which were linked with the study medication; 90% reported the tolerability of the black cohosh extract as very good or good.

CONCLUSIONS:

Black cohosh extract seems to be a reasonable treatment approach in tamoxifen treated breast cancer patients with predominantly psychovegetative symptoms.

Front Biosci (Schol Ed). 2011 Jan 1;3:191-204.

Phytotherapy as alternative to hormone replacement therapy.

Molla MD, Hidalgo-Mora JJ, Soteras MG.

Abstract

Phytoestrogens are a group of non-steroidal compounds of plant origin that present structural and functional similarities with estradiol. Isoflavones are their most widely known category. There are different mechanisms of action of isoflavones accepted, although they may be considered as selective modulators of estrogen receptors. On the other hand, Cimicifuga Racemosa is a perennial plant used traditionally for problems related to menstruation. Its action mechanisms have not been totally identified. There is a growing interest in the usefulness of phytotherapy in the treatment of symptoms and menopause-related diseases. Isoflavones and Cimicifuga Racemosa moderately improve vasomotor symptoms in menopausal women, particularly in those who have a greater number of hot flushes. Furthermore, trials performed with soy isoflavones have observed a reduction of the loss of bone mineral density in postmenopausal women and a slight decrease in LDL cholesterol. In short, phytotherapy will constitute a therapeutic option that can offer assistance to women who want to improve their quality of life through relief of vasomotor symptoms or benefit from other effects for their health.

Gynecol Endocrinol. 2009 Jan;25(1):21-6. doi: 10.1080/09513590802404005.

Cimicifuga racemosa treatment and health related quality of life in post-menopausal Spanish women.

Juliá Mollá MD, García-Sánchez Y, Romeu Sarri A, Pérez-lópez FR.

Abstract

OBJECTIVE:

The effect of Cimicifuga racemosa (CR) treatment was evaluated in healthy symptomatic post-menopausal women using the Cervantes health-related quality of life (HR-QoL) scale.

DESIGN:

A prospective observational study was carried out in 122 healthy symptomatic post-menopausal Spanish women with elevated body weight, aged between 45 and 59 years. Three groups were formed according to age intervals. Each patient completed the Cervantes HR-QoL scale before and after CR treatment (20 mg, twice a day for 3 months). Changes in Cervantes scale global quality of life scores as well as in their domains (menopause and health, psychic, sexuality and couple relationship) were analysed.

RESULTS:

The CR treatment ameliorated global quality of life in both the whole group of patients and when women were analysed by age subgroups. There were significant positive changes in Z scores for the Cervantes HR-QoL scale 'menopause and health', and 'psychic' domains in both the entire population and by age groups. The 'sexuality domain' significantly improved when the entire population was assessed, but not when each age-group was separately analysed; while there were no changes in 'couple relationship domain' scores.

CONCLUSION:

CR treatment increased both global quality of life and the four domains of the Cervantes HR-QoL scale, being an effective treatment to reduce symptoms in post-menopausal woman with elevated body weight.

PASSIFLORA

Homeopathy. 2016 Feb;105(1):84-91. doi: 10.1016/j.homp.2015.07.002. Epub 2015 Aug 29.

Open-label observational study of the homeopathic medicine Passiflora Compose for anxiety and sleep disorders.

Villet S, Vacher V, Colas A, Danno K, Masson JL, Marijnen P, Bordet MF.

Abstract

BACKGROUND:

Anxiety and sleep disorders (SDS) are frequently treated with psychotropic drugs. Health authorities in France have been advised to improve access to alternative treatments such as homeopathic medicines. Our aim was to describe the socio-demographic characteristics and clinical progression of patients prescribed homeopathic medicine Passiflora Compose (PC) for anxiety and/or SDS.

MATERIAL AND METHODS:

This was an open-label, observational study. Randomly selected general practitioners (GPs) known to prescribe homeopathic medicines recruited consecutive patients (≥18-years) prescribed PC. The following data were recorded at inclusion by the GP: socio-demographic data and anxiety severity (Hamilton anxiety rating scale or HAM-A); and by the patients: level of anxiety (STAI Spielberger self-assessment questionnaire) and SDS (Jenkins sleep scale or JSS). Anxiety and SDS were reassessed after 4 weeks of treatment using the same scales.

RESULTS:

A total of 639 patients (mean age: 46.3 ± 17.5 years; 78.6% female) were recruited by 98 GPs. Anxiety was present in 85.4% (HAM-A) and 93.3% (Spielberger State) at inclusion (mean scores: 17.8 ± 8.91 and 54.59 ± 11.69, respectively) and SDS was present in 74.0% (mean score: 15.24 ± 5.28). A total of 401 (62.7%) patients received PC alone and 167 (26.1%) PC + psychotropics. After 4 weeks, mean anxiety scores decreased by more than 7, 12 and 6 points (HAM-A, Spielberger State and Trait respectively), and SDS score by more than 4 points (JSS).

CONCLUSION:

Anxiety and/or SDS improved significantly in patients included on this study. PC could be an alternative to the use of psychotropic drugs for first intention treatment of anxiety and SDS. Further studies are needed to confirm those results.

Phytother Res. 2011 Aug;25(8):1153-9. doi: 10.1002/ptr.3400. Epub 2011 Feb 3.

A double-blind, placebo-controlled investigation of the effects of Passiflora incarnata (passionflower) herbal tea on subjective sleep quality.

Ngan A, Conduit R.

Abstract

Passiflora incarnata is a traditional herbal sedative, anxiolytic and a popular sleep aid used for the treatment of sleep disturbance. Several controlled experiments have demonstrated enhanced sleep in laboratory animals, but clinical trials in humans are lacking. The aim of the present study was to investigate the efficacy of Passiflora incarnata herbal tea on human sleep, as measured using sleep diaries validated by polysomnography (PSG). This study featured a double-blind, placebo-controlled, repeated-measures design with a counterbalanced order of treatments (passionflower vs placebo tea), separated by a 1 week 'washout' period. Forty-one participants (18-35 years) were exposed to each treatment for a week, whereby they consumed a cup of the tea and filled out a sleep diary for 7 days, and completed Spielberger's state-trait anxiety inventory on the seventh morning. Ten participants also underwent overnight PSG on the last night of each treatment period. Of six sleep-diary measures analysed, sleep quality showed a significantly better rating for passionflower compared with placebo ($t(40) = 2.70$, $p < 0.01$). These initial findings suggest that the consumption of a low dose of Passiflora incarnata, in the form of tea, yields short-term subjective sleep benefits for healthy adults with mild fluctuations in sleep quality.

Wien Med Wochenschr. 2002;152(15-16):404-6.
[Passion Flower (Passiflora incarnata L.)--a reliable herbal sedative].
Krenn L.
Abstract
Extracts and fluid extracts from the aerial parts from Passiflora incarnata L. are widely used as components of herbal sedatives. Many pharmacological investigations confirm the sedative effects of Passiflorae herba. From some of the studies also anxiolytic effects can be deduced. As Passionflower is mainly used in combinations, clinical studies of the single drug are not available. Based on pharmacological data, the experiences of traditional use and the use in combinations Passiflora extracts are an important factor in the phytotherapy of tenseness, restlessness and irritability with difficulty in falling asleep.

ZINCO

Arch Biochem Biophys. 2016 Dec 1;611:113-119. doi: 10.1016/j.abb.2016.06.003. Epub 2016 Jun 7.

Zinc and skin biology.

Ogawa Y, Kawamura T, Shimada S.

Abstract

Of all tissues, the skin has the third highest abundance of zinc in the body. In the skin, the zinc concentration is higher in the epidermis than in the dermis, owing to a zinc requirement for the active proliferation and differentiation of epidermal keratinocytes. Here we review the dynamics and functions of zinc in the skin as well as skin disorders associated with zinc deficiency, zinc finger domain-containing proteins, and zinc transporters. Among skin disorders associated with zinc deficiency, acrodermatitis enteropathica is a disorder caused by mutations in the ZIP4 transporter and subsequent zinc deficiency. The triad acrodermatitis enteropathica is characterized by alopecia, diarrhea, and skin lesions in acral, periorificial, and anogenital areas. We highlight the underlying mechanism of the development of acrodermatitis because of zinc deficiency by describing our new findings. We also discuss the accumulating evidence on zinc deficiency in alopecia and necrolytic migratory erythema, which is typically associated with glucagonomas.

Int J Dermatol. 2016 Jan;55(1):24-9. doi: 10.1111/ijd.12769. Epub 2015 Jul 3.

Evaluation of serum zinc level in patients with newly diagnosed and resistant alopecia areata.

Abdel Fattah NS, Atef MM, Al-Qaradaghi SM.

Abstract

BACKGROUND:

Alopecia areata (AA) is a non-scarring, autoimmune, inflammatory hair loss disease. Zinc is a trace element involved in important functional activities of hair follicles.

PURPOSE:

To evaluate serum zinc levels in patients with newly diagnosed and resistant lesions of AA in comparison to age- and sex-matched healthy controls.

METHODS:

The present study included 100 subjects: 50 patients with AA divided into two equally distributed subgroups (25 patients with recent onset AA [subgroup 1] and 25 patients with resistant AA [subgroup 2]) and 50 age- and sex-matched healthy controls. Serum zinc levels were assessed in all subjects. Comparison of mean serum zinc levels was done between all patients and controls, between patients' subgroups as well as between patient's subgroup and controls. Correlations between serum zinc level and extent of AA and its duration were also done in all patients and each patient's subgroup.

RESULTS:

A significantly lower serum zinc level was found in patients with AA compared with controls and was significantly lower in patients with resistant AA compared to patients with newly diagnosed AA. Significant inverse correlations existed between serum zinc level, severity of AA, and disease duration in all patients as well as in patients with resistant AA.

CONCLUSION:

Lower serum zinc level existed in patients with AA and correlated inversely with disease duration, severity of AA, and its resistance to therapies. Therefore, assessment of serum zinc level in patients with AA appears useful as a marker of severity, disease duration, and resistance to therapies. Accordingly, zinc supplements may provide a therapeutic benefit.

Acta Derm Venereol. 2014 Sep;94(5):558-62. doi: 10.2340/00015555-1772.

Hair zinc levels and the efficacy of oral zinc supplementation in patients with atopic dermatitis.

Kim JE, Yoo SR, Jeong MG, Ko JY, Ro YS.

Abstract

Zinc deficiency in patients with atopic dermatitis (AD) and the use of zinc supplementation is still controversial. We measured hair zinc levels in 58 children with AD and 43 controls (age range 2-14 years). We also investigated the efficacy of oral zinc supplementation in AD patients with low hair zinc levels by comparing eczema assessment severity index (EASI), transepidermal water loss (TEWL), and visual analogue scales for pruritus and sleep disturbance in patients receiving zinc supplementation (Group A) and others not receiving supplementation (Group B). At baseline, the mean zinc level was significantly reduced in AD patients (113.1 μg/g vs. 130.9 μg/g, $p = 0.012$). After 8 weeks of supplement, hair zinc level increased significantly in Group A ($p < 0.001$), and EASI scores, TEWL, and visual analogue scales for pruritus improved more in Group A than in Group B ($p = 0.044$, 0.015 and < 0.001, respectively). Thus, oral zinc supplementation may be effective in AD patients with low hair zinc levels.