
Efficacy of isoflavones in relieving vasomotor menopausal symptoms: a systematic review

Jacobs A, Wegewitz U, Sommerfeld C, Grossklau R, Lampen A

CRD summary

This review found no conclusive evidence that treatment with soy isoflavone supplementation improved vasomotor symptoms in perimenopausal and postmenopausal women. Given the variation between studies and poor study quality, these cautious conclusions appear reasonable; however, there was some risk that relevant data were missed.

Authors' objectives

To investigate the efficacy of isoflavone supplements for the reduction of vasomotor symptoms in menopausal women.

Searching

Searches of 70 databases (from the German Institute of Medical Documentation and Information) were conducted to identify studies published in any language up to March 2008. Search terms were reported. References of relevant reviews were searched. Further details of the search strategy were available in an online appendix.

Study selection

Randomised placebo controlled trials (of at least 12 weeks duration) of dietary supplements that contained extracted or purified soy and red clover (as monotherapy administered as a supplement or isoflavone-enriched food) for the treatment of vasomotor menopausal symptoms were eligible for inclusion. Perimenopausal women and postmenopausal women (as defined in the review) who had vasomotor symptoms at baseline and women who reported spontaneous or surgical menopause were eligible for inclusion. Patients who had cancer, a history of cancer, a major disease or who used tamoxifen or menopausal hormone therapy (MHT) a month before the intervention were excluded. Eligible outcome measures were individual vasomotor symptoms, vasomotor scales or sub-scales of scores and composite scores of vasomotor symptoms.

This review focused on studies of soy isoflavones. The included studies investigated isolated genistein (54mg/day), soy extract or soy protein powder (39 or 120mg/day soy isoflavones); one study assessed daidzein rich isoflavones. Basal hot flush frequency varied between studies. Time since participants' last period was at least six months or at least 12 months in most of the included studies. Study duration ranged from 12 weeks to one year. The outcomes reported were hot flush frequency and severity and adverse events.

The authors did not state how many reviewers selected papers for inclusion.

Assessment of study quality

Validity was assessed independently by two reviewers using criteria of randomisation, blinding, allocation concealment, baseline comparability, number of analysed participants, dropouts, analysis and reporting. Disagreements were resolved by consensus or discussion with a third reviewer. Each criterion was graded A (met), B (not reported/unclear) or C (inadequate); further details were available in the review.

Data extraction

Data were extracted for vasomotor symptoms (hot flush frequency or severity) or adverse events by two reviewers. Disagreements were resolved by consensus or discussion with a third reviewer.

Methods of synthesis

The studies were presented in a narrative synthesis grouped by type of soy intervention. A correlation analysis was performed to investigate influences of initial hot flush as well as isoflavone doses. This was performed for all studies and separately for studies with known and unknown aglycone content. Crossover studies were analysed only in the first phase.

Results of the review

Seventeen RCTs (n=1,871) were included in the review. Five studies adequately reported randomisation, 10 gave information about method of treatment, three described allocation concealment, five described baseline comparability, 10 had a dropout rate of 20% or less and two performed intention-to-treat analyses. The number of criteria (out of eight) that were graded A was: one in two studies; two in four studies; three in six studies; four in four studies; and five in one study. Twenty-three studies met the inclusion criteria, but only 17 were included in the analysis as six isoflavone studies were included in several other meta-analyses; these were not discussed in detail

Genistein studies (two studies; one was a subgroup analysis): Both RCTs found a significant improvement in hot flush frequency with 54mg genistein.

Soy extract (11 studies): Three out of eight trials found improved hot flush frequency with isoflavones compared with placebo. Five of eight trials found significant improvement in hot flush severity after soy supplement consumption.

Soy protein powder (four studies): One of four studies reported a reduction in hot flush frequency with isoflavones. The three studies that evaluated hot flush severity found no significant reduction.

Adverse events: No proliferative effects of soy isoflavones on the endometrium, vagina or breast tissue was reported in any of the studies. Gastrointestinal disorders occurred after treatment in several studies, but a significant difference between placebo and soy was found in only one study.

No correlation was found between initial hot flushes and outcome.

Authors' conclusions

There was no conclusive evidence that treatment with soy isoflavone supplementation improved vasomotor symptoms in perimenopausal and postmenopausal women.

CRD commentary

The research question was supported by well-defined inclusion criteria. Numerous databases were searched for studies published in any language. Some relevant studies may have been missed as only published studies were eligible for inclusion in the review. Validity assessment and data extraction were performed in duplicate, which reduced risks of error and bias; it was unclear whether similar precautions were taken during study selection. Study validity was assessed with appropriate criteria and were found to be generally of poor quality; this was taken into consideration in the analysis. Narrative synthesis appeared appropriate given the heterogeneity between studies in participants and outcomes.

Given the variation between studies and poor study quality, the authors' cautious conclusions appear reasonable; however, there was some risk that relevant data were missed.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that systematic reviews of long-term studies that investigated the safety of soy isoflavone supplements were required to determine adverse effects.

Funding

Not stated.

Bibliographic details

Jacobs A, Wegewitz U, Sommerfeld C, Grossklaus R, Lampen A. Efficacy of isoflavones in relieving vasomotor menopausal symptoms: a systematic review. *Molecular Nutrition and Food Research* 2009; 53(9): 1084-1097

PubMedID

19653225

DOI

10.1002/mnfr.200800552

Original Paper URL

<http://onlinelibrary.wiley.com/doi/10.1002/mnfr.200800552/abstract>

Additional Data URL

<http://onlinelibrary.wiley.com/doi/10.1002/mnfr.200800552/supinfo>

Indexing Status

Subject indexing assigned by NLM

MeSH

Female; Genistein /therapeutic use; Hot Flashes /drug therapy; Humans; Isoflavones /therapeutic use; Menopause; Plant Extracts /therapeutic use; Randomized Controlled Trials as Topic; Soybeans

AccessionNumber

12009110286

Date bibliographic record published

14/04/2010

Date abstract record published

20/10/2010

Record Status

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.