
Vasomotor symptom relief by soy isoflavone extract tablets in postmenopausal women: a multicenter, double-blind, randomized, placebo-controlled study.


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OBJECTIVE: To determine the safety and efficacy of an oral soy isoflavone extract for relief of menopausal hot flushes. DESIGN: This was a double-blind, randomized, parallel group, outpatient, multicenter (15 sites) study. A total of 177 postmenopausal women (mean age = 55 years) who were experiencing five or more hot flushes per day were randomized to receive either soy isoflavone extract (total of 50 mg genistin and daidzin per day) or placebo. Physical examinations and endometrial and biochemical evaluations were performed upon admission and completion. Body weight, symptoms, and safety were evaluated at all visits. RESULTS: Relief of vasomotor symptoms was observed in both groups. Decreases in the incidence and severity of hot flushes occurred as soon as 2 weeks in the soy group, whereas the placebo group experienced no relief for the first 4 weeks. Differences between evaluable subjects in both groups were statistically significant over 6 weeks (p = 0.03). Over 12 weeks, between-group differences approached significance (p = 0.08). Endometrial thickness evaluated by ultrasound, lipoproteins, bone markers, sex hormone-binding globulin and follicle-stimulating hormone, and vaginal cytology did not change in either group. CONCLUSIONS: Soy isoflavone extract was effective in reducing frequency and severity of flushes and did not stimulate the endometrium. Soy isoflavone extracts provide an attractive addition to the choices available for relief of hot flushes. PMID: 10914616 [PubMed - indexed for MEDLINE]