Effects of a standardized soy extract on hot flushes: a multicenter, double-blind, randomized, placebo-controlled study.

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OBJECTIVE: To investigate the effect of an oral soy isoflavone extract (Phytosoya) on hot flushes in menopausal women. DESIGN: The study was conducted on outpatients according to a multicenter, randomized, double-blind, placebo-controlled, parallel-group design. A total of 75 patients in natural or surgical menopause suffering from at least seven hot flushes per day were randomized to receive during 4 months either soy isoflavone extract (total of 70 mg genistin and daidzin per day) or placebo. RESULTS: There is evidence to suggest that 16 weeks of treatment with soy extract can help reduce the mean number of hot flushes per 24 hours in menopausal women. Withdrawals during this trial made it difficult to obtain an unbiased estimate of the true treatment effect, but numerous sensitivity analyses lend support to the suggestion that taking soy extract can be beneficial in the treatment of hot flushes. In particular, women taking soy extract had a 38% reduction in the mean number of hot flushes by week 4 and a 51% reduction by week 8. By the end of week 16, patients taking soy extract had a 61% reduction in their daily hot flushes versus a 21% reduction obtained with the placebo. "Responders" (defined as patients whose hot flushes were reduced by at least 50% at the end of treatment period) were 65.8% in the soy extract group and 34.2% in the placebo group ( < 0.005). CONCLUSION: Soy isoflavone extract may help to reduce the frequency of hot flushes in climacteric women and provides an attractive addition to the choices available for relief of hot flushes.

PMID: 12218721 [PubMed - indexed for MEDLINE]