Effects of the phytoestrogen genistein on hot flushes, endometrium, and vaginal epithelium in postmenopausal women: a 1-year randomized, double-blind, placebo-controlled study

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Abstract

Objective: To evaluate in a 12-month, prospective, randomized, double-blind, placebo-controlled study whether pure administration of the phytoestrogen genistein (54 mg/d) might reduce the number and severity of hot flushes in postmenopausal women with no adverse effect on the endometrium.

Design: A total of 389 participants met the main study criteria and were randomly assigned to receive the phytoestrogen genistein (n = 198) or placebo (n = 191). About 40% of participants in both groups did not suffer from hot flushes, and the evaluation was performed in a subgroup of 247 participants (genistein, n = 125; placebo, n = 122). Reductions from baseline in the frequency and severity of hot flushes were the principal criteria of efficacy. Endometrial thickness was evaluated by ultrasonography. The maturation value was also used to determine hormonal action on the vaginal cells.

Results: There were no significant differences in age, time since menopause, body mass index, and vasomotor symptoms between groups at baseline (4.4 T 0.33 hot flushes per day in the genistein group and 4.2 T 0.35 hot flushes per day in the control group). The effect was already evident in the first month and reached its peak after 12 months of genistein therapy (56.4% reduction in the mean number of hot flushes). Furthermore, there was a significant difference between the two groups at each evaluation time (1, 3, 6, and 12 months). No significant difference was found in mean endometrial thickness and maturation value score between the two groups, either at baseline or after 12 months.

Conclusions: The phytoestrogen genistein has been shown to be effective on vasomotor symptoms without an adverse effect on endometrium.

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