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Efficacy and safety of DT56a compared to hormone therapy in Greek post-menopausal women.

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Abstract

BACKGROUND:

Hormone therapy (HT) is the treatment of choice for the alleviation of menopausal symptoms; concerns, however, about its concomitant long-term health risks have limited its use. DT56a is a unique enzymatic isolate of soybeans. The purpose of our study was to evaluate the efficacy and safety of DT56a, compared to HT, in symptomatic post-menopausal women.

SUBJECTS AND METHODS:

Eighty-nine post-menopausal women were studied prospectively. Women with climacteric symptoms were randomly assigned to receive eitherDT56a (no.=27) or oral low dose continuous combined HT (no.=26). Symptomatic women not wishing to receive any treatment served as controls (no.=36). Menopausal symptoms as assessed through the Kupperman index, serum lipids and lipoproteins, calcium, as well as bone mineral density (BMD), endometrial thickness, and mammography were assessed at baseline and at 12 months.

RESULTS:

Patients receiving HT and DT56a showed a significant and independent decrease in menopausal symptoms (mean difference in Kupperman score, DT56a group: -3.98, HT group -5.601, no treatment group +1.76, p-value <0.001). Lumbar spine BMD T-score was significantly lower in women receiving no treatment, as opposed to the two treatment arms which showed no significant change (No treatment, baseline: -0.60, final: -0.85, p=0.001; HT, baseline: -84, final -0.99, p=0.79; DT56a, baseline -0.51, final: -0.76, p=0.75). No differences in femoral bone density, ET or mammography classification were detected in any of the treatment arms. Likewise, serum lipids or lipoproteins did not differ between the three groups.

CONCLUSIONS:

DT56a decreased menopausal symptoms significantly and in the same degree as HT