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Tofupill/Femarelle (DT56a): a new phyto-selective estrogen receptor modulator-like substance for the treatment of postmenopausal bone loss.

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Abstract

OBJECTIVE:

To evaluate the efficacy of Tofupill/Femarelle (DT56a), a novel phyto-selective estrogen receptor modulator (SERM), in preserving bone mineral density (BMD) in postmenopausal women.

DESIGN:

The study sample consisted of 98 healthy, postmenopausal women who were randomly allocated, on a double-blind basis, to receive either 644 mg/d DT56a (study group) or 344 mg/dDT56a supplemented with calcium (low-dose group) for 12 months. Each participant was assessed with a comprehensive health questionnaire, a detailed physical, and laboratory and pelvic sonogram examinations at entry and every 3 months thereafter. BMD was assessed by dual-energy x-ray absorptiometry (Lunar) of the lumbar spine and femoral neck before the study began and after 12 months of treatment.

RESULTS:

After 12 months of treatment, BMD had increased in the study group by 3.6% in the lumbar spine ($P = 0.039$) and by 2.0% in the femoral neck (NS). In the low-dose group, BMD had decreased in the lumbar spine by 0.6% (NS) and by 0.6% in the femoral neck (NS). Comparison of the change in bone density between the groups yielded a significant difference for the lumbar spine ($P = 0.037$). Neither group showed a change in endometrial thickness and sex hormone levels nor reported any side effects of treatment.

CONCLUSIONS:

Femarelle treatment in postmenopausal women increases BMD without unwanted estrogenic effect. Femarelle appears to be a promising phyto-SERM for the prevention of postmenopausal osteoporosis

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