Hammar, M. Christau, S. Nathorst-Böös, J. Rud, T. Garre, K.

A double-blind, randomised trial comparing the effects of tibolone and continuous combined hormone replacement therapy in postmenopausal women with menopausal symptoms.

Br J Obstet Gynaecol 105:904-11; 1998

From the Department of Obstetrics and Gynaecology, University Hospital, Linköping, Sweden.

OBJECTIVE: To compare the effects of two postmenopausal regimens on menopausal symptoms, bleeding episodes, side effects and acceptability. DESIGN: Double-blind, randomised controlled trial.

SETTING: Twenty-nine sites in Denmark, nine in Norway and six in Sweden. PARTICIPANTS: Four hundred and thirty-seven postmenopausal women with menopausal complaints. None of these women had had a hysterectomy. INTERVENTIONS: Daily treatment with tibolone 2.5 mg (n = 218) or 17beta-oestradiol 2 mg plus norethisterone acetate 1 mg (E2/NETA) (n = 219). MAIN OUTCOME MEASURES: Hot flushes, sweating episodes, vaginal dryness, assessment of sexual life and bleeding patterns; at baseline and after 4, 12, 24 and 48 weeks.

RESULTS: Treatment with either preparation significantly reduced mean scores for hot flushes, sweating episodes and vaginal dryness. The overall discontinuation rate was 28% (tibolone 25%, E2/NETA 31%; P = 0.14), mostly during the first six months. There was a markedly lower cumulative incidence of bleeding or spotting episodes with tibolone compared with E2/NETA (P < 0.0001), mainly during the first six treatment cycles.

CONCLUSIONS: Both tibolone and E2/NETA effectively alleviate menopausal symptoms. However, tibolone caused significantly fewer bleeding or spotting episodes, which were reflected by lower overall rates of bleeding, as well as lower drop-out rates due to bleeding.

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