

Lundström E, Christow A, Kersemaekers W, Svane G, Azavedo E, Söderqvist G, Mol-Arts M, Barkfeldt J, von Schoultz B.

Effects of tibolone and continuous combined hormone replacement therapy on mammographic breast density.

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OBJECTIVE: Our purpose was to compare the effects of tibolone, continuous combined hormone replacement therapy, and placebo on mammographic breast density.

STUDY DESIGN: A prospective, randomized, double-blind placebo-controlled study was performed. A total of 166 postmenopausal women were equally randomized to receive tibolone 2.5 mg, estradiol 2 mg/norethisterone acetate 1 mg (E(2)/NETA), or placebo. Mammograms were performed at baseline and after 6 months of treatment. Mammographic density was quantified according to the Wolfe classification and by the percentage area of the breast that had a dense pattern.

RESULTS: An increase in mammographic density was much more common among women receiving continuous combined hormone replacement therapy (46%-50%) than among those receiving tibolone (2%-6%) and placebo (0%) treatment. The difference between E(2)/NETA and placebo was highly significant ($P < .001$). Treatment with tibolone did not differ from that with placebo. The relative risk of an increase in breast density for E(2)/NETA versus tibolone was found to be 8.3 (95% CI 2.7-25.0).

CONCLUSION: An increase in mammographic density should be regarded as an unwanted side effect of hormone replacement therapy. In contrast to estrogen/progestogen treatment, tibolone seems to exert little stimulation of breast tissue.

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