- **Title:** Testosterone inhibits estrogen/progestogen-induced breast cell proliferation in postmenopausal women.
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- **Source:** Menopause (10723714) (MENOPAUSE), 2007 Mar-Apr; 14(2): 183-190. (8p)
- Publication Type: Journal Article clinical trial, research

Language: English

 Major Subjects:
 Breast -- Drug Effects

 Hormone Replacement Therapy

 Postmenopause

 Testosterone -- Administration and Dosage

- Minor Subjects: Administration, Transcutaneous; Aged; Biopsy, Needle; Breast --Pathology; Breast Neoplasms -- Pathology; Breast Neoplasms --Prevention and Control; Cell Physiology -- Drug Effects; Estradiol --Administration and Dosage; Estradiol -- Blood; Female; Immunohistochemistry; Somatomedins; Middle Age; Steroids --Administration and Dosage; Steroids -- Blood; Testosterone -- Blood; Treatment Outcomes; Human
 - Abstract: Objective: During the past few years serious concern has been raised about the safety of combined estrogen/progestogen hormone therapy, in particular about its effects on the breast. Several observations suggest that androgens may counteract the proliferative effects of estrogen and progestogen in the mammary gland. Thus, we aimed to study the effects of testosterone addition on breast cell proliferation during postmenopausal estrogen/progestogen therapy.Design: We conducted a 6-month prospective, randomized, double-blind, placebo-controlled study. A total of 99 postmenopausal women were given continuous combined estradiol 2 mg/norethisterone acetate 1 mg and were equally randomly assigned to receive additional treatment with either a testosterone patch releasing 300 [mu]g/24 hours or a placebo patch. Breast cells were collected by fine needle aspiration biopsy at baseline and after 6 months, and the main outcome measure was the percentage of proliferating breast cells positively stained by the Ki-67/MIB-1 antibody.Results: A total of 88 women, 47 receiving active treatment and 41 in the placebo group, completed the study. In the placebo group there was a more than fivefold increase (P < 0.001) in total breast cell proliferation from baseline (median 1.1%) to 6 months (median 6.2%). During testosterone addition, no significant increase was recorded (1.6% vs 2.0%). The different effects of the two treatments were apparent in both epithelial and stromal cells.Conclusions: Addition of testosterone may counteract breast cell proliferation as induced by estrogen/progestogen therapy in postmenopausal women.

EBSCOhost

Journal Subset: Biomedical; Peer Reviewed; USA

ISSN: 1072-3714

MEDLINE Info: PMID: 17108847 NLM UID: 9433353

Grant Information: Swedish Cancer Society, the Swedish Research Council (project 5982), and the Karolinska Institutet Research Funds

Entry Date: 20080111

Revision Date: 20150711

Accession Number: 105926072

Database: CINAHL Complete