

Breast tenderness during hormone replacement therapy linked to elevated cancer risk

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Women who developed new-onset breast tenderness after starting estrogen plus progestin hormone replacement therapy were at significantly higher risk for developing breast cancer than women on the combination therapy who didn't experience such tenderness, according to a new UCLA study.

The research, published in the Oct. 12 issue of the *Archives of Internal Medicine*, is based on data from more than 16,000 participants in the Women's Health Initiative estrogen-plus- [progestin](#) clinical trial. This trial was abruptly halted in July 2002 when researchers found that healthy menopausal women on the combination therapy had an elevated risk for invasive [breast cancer](#).

Researchers do not know why breast tenderness indicates increased cancer risk among women on the combination therapy, said the new study's lead researcher, Dr. Carolyn J. Crandall, a clinical professor of general internal medicine and health services research at the David Geffen School of Medicine at UCLA.

"Is it because the hormone therapy is causing breast-tissue cells to multiply more rapidly, which causes breast tenderness and at the same time indicates increased cancer risk? We need to figure out what makes certain women more susceptible to developing breast tenderness during hormone therapy than other women," Crandall said.

This study compared the daily use of oral conjugated equine estrogens (0.625 mg) plus medroxyprogesterone acetate (2.5 mg), or CEE+MPA, with the daily use of a [placebo](#) pill.

Of the participants in the trial, 8,506 took estrogen plus progestin and 8,102 were given placebos. Participants underwent mammography and clinical breast exams at the start of the trial and annually thereafter. Self-reported breast tenderness was assessed at the beginning of the trial and one year later, and [invasive breast cancer](#) over the next 5.6 years was confirmed by medical record review.

Women on the combination therapy who did not have breast tenderness at the trial's inception were found to have a threefold greater risk of developing tenderness at the one-year mark, compared with participants who were assigned placebos (36.1 percent vs. 11.8 percent). Among the women who did report breast tenderness at the beginning, the risk at one-year was about 1.26 times that of their counterparts on placebos.

Of the women who reported new-onset breast tenderness, 76.3 percent had been on the combination therapy.

Women in the combination therapy group who did not have breast tenderness at the outset but experienced new-onset tenderness at the first annual follow-up had a 48 percent higher risk of invasive breast cancer than their counterparts on combination therapy who did not have breast tenderness at the first-year follow-up.

"To our knowledge, no prior published studies have addressed whether there is an association between CEE+MPA-induced new-onset breast tenderness and breast cancer risk," Crandall said.

The study does have limitations. The data the researchers used assessed breast tenderness only annually and thus could have underestimated it.

Also, the rates of [women](#) discontinuing the combination therapy and switching from placebos to active therapy were relatively high, though the researchers believe this could have decreased, rather than increased, the observed association between new-onset tenderness and cancer risk. And the results don't apply to other types of [estrogen](#) or progestin therapy.

Source: University of California - Los Angeles

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