

# New evidence of hormone therapy causing breast cancer, professor says

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Postmenopausal women who take combined estrogen plus progestin menopausal hormone therapy for at least five years double their annual risk of breast cancer, according to new analyses from a major study that clearly establishes a link between hormone use and breast cancer, Stanford researchers say. The multi-center study also found that women on hormones can quickly reduce their risks of cancer simply by stopping the therapy.

The study is a follow-up to the landmark Women's Health Initiative report of 2002, which found that postmenopausal women taking estrogen plus progestin were at far greater risk of developing breast cancer and other serious conditions than women on placebo.

After publication of the WHI data, use of hormone therapy plummeted in the United States - from 60 million prescriptions in 2001 to 20 million in 2005. Breast cancer rates also declined significantly within the year, suggesting a strong link between hormone use and cancer risk. But some scientists still questioned the connection, saying the dip in breast cancer rates could not have occurred so rapidly and may have been related to patterns of mammogram use.

The latest study, however, should put those questions to rest, said Marcia Stefanick, PhD, professor of medicine at Stanford University School of Medicine and a co-author of the study.

"This is very strong evidence that estrogen plus progestin causes breast

cancer," said Stefanick, chair of the WHI executive committee. "You start women on hormones and within five years, their risk for breast cancer is clearly elevated. You stop the hormones and within one year, their risk is essentially back to normal. It's reasonably convincing cause-and-effect data."

The results, she cautioned, do not apply to women taking estrogen alone. The large WHI trial of estrogen-only did not find an increase in breast cancer for the majority of women assigned to estrogen-only therapy.

Results of the latest multi-center study are to be published in the Feb. 5 issue of the *New England Journal of Medicine*.

In the study, the researchers analyzed data from two groups of women. In one instance, they continued to follow more than 15,000 women in the original landmark trial, which was halted three years early by its sponsor, the National Institutes of Health. The women in this trial had been randomly assigned to take either combined hormone therapy or a placebo. When the negative results emerged in 2002, the women were all advised to stop taking their pills. The researchers continued to monitor them, taking note of the timing and number of any new breast cancer cases and how often the women received mammograms.

In addition, the researchers looked at data collected for 41,449 women who were enrolled in a separate WHI observational study begun in 1994. These were "real world women" who could make their own choices as to whether they would take hormones or not. About 40 percent of the women in this group were on hormone therapy when the study began and had been taking the hormones an average of 6.9 years. The women weren't given any special instructions about hormone use after the 2002 study came out, but they did receive a letter outlining the results. They were also encouraged to continue to have regular mammograms.

The results from the two groups of women were quite similar, the researchers found. In the clinical trial, the incidence of breast cancer was much higher in the hormone group in the five years leading up to 2002. But after they stopped taking the hormones, breast cancer rates dropped very rapidly. The number of breast cancer diagnoses fell 28 percent within the year. Use of mammography remained the same for all the women during all phases of the trial, the researchers found.

Although women in the observational study received no specific advice to stop hormone therapy, many voluntarily chose to do so, reflecting what women were doing across the United States. There was a 50 percent decrease in hormone use among these women between 2000 and 2003, which coincided with a 43 percent reduction in their breast cancer rates between 2002 and 2003, the researchers reported.

The overall results were not affected by mammography use, the researchers concluded. Some scientists had argued that women taking hormones were more likely to get mammograms, leading to more frequent detection of tumors. While that is true, hormone use also can make it difficult to detect small tumors with mammography because of changes that occur in the breast, Stefanick noted.

"Our data suggest that although you are picking up more tumors in those women, you're probably missing a lot as well because of the problems in using mammography in women taking hormones," she said. Those problems disappear once the women stop using hormones, as breast tissue returns to normal, she said.

Source: Stanford University Medical Center

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