

Cancer risk slightly higher for women in discontinued hormone treatment trial

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A follow up study of participants in the Women's Health Initiative (WHI) clinical trial led by a University of North Carolina at Chapel Hill researcher has found that women who were taking the combined hormone therapy of estrogen plus progestin may have an increased risk of cancer since the intervention was stopped, compared to participants in the trial's placebo group.

However, the increased risks of heart disease, stroke and blood clots – which had been seen in women taking the therapy as part of the WHI trial – have diminished in the three years since researchers stopped it, according to a study published in the March 5 issue of the *Journal of the American Medical Association*.

The study's lead author is Dr. Gerardo Heiss, a Kenan professor of epidemiology in the UNC School of Public Health.

The WHI trial of estrogen plus progestin – which included 16,608 healthy postmenopausal women – was originally designed to study what effect the hormone treatment would have on cardiovascular disease, cancer risks and bone fractures.

The trial was stopped in July 2002 after participants had been on the therapy for an average of 5.6 years because researchers saw an increased risk of breast cancer and cardiovascular disease in women randomly assigned to hormone therapy, compared with those who received a placebo.

Since then, Heiss and other WHI researchers at collaborating institutions have examined the risks and benefits experienced by 15,730 trial participants who had follow-up visits from July 2002 to March 2005, after they stopped hormone therapy.

Researchers have found that the yearly event rates for the outcome "all cancer" was higher for

the estrogen plus progestin group (1.56 percent per year [n = 281]) than the placebo group (1.26 percent per year [n = 218]). This reflects a greater risk of invasive breast cancer and other cancers in the estrogen plus progestin group. Although the risk of breast cancer remained elevated during the follow-up, the risk was less than that experienced towards the end of the trial period.

"The WHI investigators did not expect to find an increased overall risk of cancer after stopping the estrogen plus progestin," Heiss said. "The increased risk is small, but the follow up did indicate there are higher levels of breast cancer, lung cancer, stroke and death among those who had taken this therapy. Thus, there is a need for prevention efforts through healthy lifestyle choices, risk factor control and regular screening activities as recommended by health care practitioners. This is good advice for everyone though, whether they have taken estrogen plus progestin for 3.5 to 8.5 years – as in this study – or not."

A summary of the risks and benefits (called the global index) included outcomes for coronary heart disease, invasive breast cancer, stroke, pulmonary embolism, endometrial cancer, colorectal cancer, hip fracture and death due to other causes. The researchers found that this measure was 12 percent higher in women randomly assigned to receive estrogen plus progestin compared with the placebo, and did not visibly change after the intervention was stopped.

The rates of colorectal cancer did not differ significantly between the two groups and rates of endometrial cancer were lower in the estrogen plus progestin group.

The risk of cardiovascular events was comparable between the two groups in the follow up assessment, Heiss said, meaning that the increased risks seen in women assigned to estrogen plus progestin during the trial period

weakened after the study drugs were stopped.

The risk of fractures during the postintervention follow-up was similar among women in both groups for each type of fracture considered: hip, vertebral and other osteoporotic fractures.

“The follow-up after stopping estrogen plus progestin use confirms the trial’s main conclusion that combination hormone therapy should not be used to prevent disease in healthy, postmenopausal women,” Heiss said. “The most important message to women who have stopped this hormone therapy is the need for continued prevention and screening activities through their physicians, for all important preventable conditions.”

Source: University of North Carolina at Chapel Hill

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