



Message from The President on the Women's Health Initiative Study

- NIH Halts Estrogen-only Study -

On March 2, 2004, the National Institutes of Health (NIH) announced that it has asked the 11,000 postmenopausal women who participated in the estrogen-alone study of the Women's Health Initiative (WHI) to stop taking their medication and begin the follow-up phase of the study.

Why Was the Study Stopped?

After reviewing the data from 7 years of the study, the NIH concluded that estrogen alone does not appear to increase or decrease heart disease – one of the main points of the study – and that the results from the estrogen-only study would likely not change if the trial continued until its planned completion date of 2005. Furthermore, the study showed a small increase in the risk of strokes, which put healthy women at risk and made it unacceptable to continue with the study. Also, the study showed no increased risk for breast cancer and a decrease in the risk of hip fractures.

What Was the Women's Health Initiative Study Designed to Do?

The estrogen-alone study was part of a larger study designed to evaluate the risks and benefits of hormone therapy for postmenopausal women, focusing particularly on the long-term effects of hormone therapy on the prevention of heart disease and hip fractures, and on monitoring possible increases in risk for breast and colon cancer. The study was not designed to evaluate the benefits of hormone treatment on hot flashes and vaginal dryness.

In the overall WHI study, the combination of estrogen and progestin was given to women who had a uterus (estrogen alone is known to increase the risk of uterine cancer, which is prevented when progestin is given with the estrogen). Estrogen only was given to women who had had their uterus removed before the study began (a hysterectomy).

How Do the Results of the Estrogen-only and Estrogen-Progestin studies compare?

The estrogen-only study showed no increased risk or benefit to heart disease and no increased risk of breast cancer. By comparison, the estrogen-progestin study showed an increased risk in both of these.

In both studies, however, there was a decreased risk in hip fractures and a slight increase in the risk of stroke (8 women for every 10,000 in the study).

The Women's Health Initiative Memory Study (WHIMS)

Additionally, there was a smaller subset of women who were evaluated for effects on memory and cognition. This was called the WHIMS study (Women's Health Initiative Memory Study). The NIH concluded that there was a trend toward an increased risk of probable dementia and mild cognitive impairment. However, it should be kept in mind that the women in this study began taking hormones at a later age than the majority of women initiating hormone treatment.

What Should You Do With This Information?

The U.S. Food and Drug Administration recommends that hormone treatment should be used for the shortest length of time and at the lowest doses possible for the management of moderate to severe menopause symptoms.

The Hormone Foundation supports the FDA's recommendations and encourages each postmenopausal woman to discuss with her doctor the best treatment for her, taking into account her medical and family history, and the risks and benefits associated with each treatment option.

What's Next?

WHI researchers will publish the results of the estrogen-only arm of the study, as well as the WHIMS study. In accordance with our commitment to provide the most reliable and up-to-date information for the public, The Hormone Foundation will review the results and make additional information available to the public.

For more information, visit the [Menopause](#) section on this site. To find a reproductive endocrinologist, visit our online [physician referral](#) listing.

Additional Resources

- NIH press release - <http://www.nhlbi.nih.gov/new/press/04-03-02.htm>
- WHI Study Website - <http://www.nhlbi.nih.gov/whi/>
- American College of Obstetricians and Gynecologists Website - <http://www.acog.org/>
- American Society for Reproductive Medicine - <http://www.asrm.org>
- North American Menopause Society - <http://www.menopause.org>

The Hormone Foundation - March 5, 2004