



WHI HRT *Update*

2000

WHAT YOU SHOULD KNOW ABOUT HORMONES AND CARDIOVASCULAR HEALTH

Our promise to you: When you joined the Women's Health Initiative, we promised to tell you about new research findings related to hormones and your health. In the past we gave you "WHI Updates" to keep you informed. In this "Update" we are providing some new, early information about how female hormones might affect women's risk for heart attack, stroke, and blood clots in the legs and lungs. Because this information was not known when you entered the study, the Data and Safety Monitoring Board (DSMB) has recommended that we tell you about it. As it has done after each review of the study data, the DSMB has recommended continuation of the study.

New Information from the WHI

Before, we have told you about findings from other studies that looked at how hormones may affect women's health. The information in this update actually comes from the WHI Hormone Program.

Current data from the WHI suggests that during the first two years there was a small increase in the number of heart attacks, strokes, and blood clots in women taking active hormones compared to inactive (placebo) pills. Over time, these differences seem to get smaller and may even disappear. In fact, overall, WHI women had fewer such events than would be expected in the general population.

Your Safety is Our First Concern

We monitor your safety in many different ways. Our clinic staff evaluates your health at least every six months to make sure it is safe for you to stay on study pills. A local human subjects committee also reviews WHI activities here. Our DSMB reviews

information collected from clinics around the country every six months to make sure the study is safe. The DSMB is an independent group of medical experts who are not WHI researchers. Both your local clinic's human subjects committee and the DSMB have the power to stop or change the study if they find important safety concerns. They have not done so. In fact, the DSMB has recommended that the study continue.

Timing is Everything

As with all clinical trials, we are seeing new information as this study goes on. Some of this information was not expected at the time the trial started. We want to share this information with you. Most of the earlier studies reported that hormones reduced a woman's risk of heart disease over time. The consent you signed for the Hormone Program did not talk about a possible initial increased risk of heart attack or stroke. The consent did have information about possible blood clots in the legs and lungs. Because the differences were so small between the

women on hormones compared to women on placebo pills, they only became apparent after most of you had been in the trial for two years.

Designed to last for up to 11 years, the WHI will provide us with important answers to questions about women's health -- questions that were not addressed by earlier studies.

Findings from "HERS"

In earlier updates, we told you about HERS (Heart and Estrogen/progestin Replacement Study). In HERS, women who already had heart disease took active hormones or placebo pills for just over four years. HERS, like earlier studies, found that women taking hormones were more likely to have blood clots in their legs and lungs.

HERS also found that women taking active hormones had more heart attacks during the first year than women taking placebo pills. After two or more years, the women taking active hormones had fewer heart attacks than women taking placebo pills. By the end of the study, there was no overall difference in heart attacks between the groups.

The early findings from the WHI are similar to HERS. Unlike WHI, HERS lasted only four years. Thus, HERS could not examine hormone effects over many years. Also,

WHI women are generally healthy, and HERS women all had heart disease. Consequently, heart problems were much less frequent in WHI than in HERS.

What This Means for You

These early WHI findings mean that the general picture of possible risks and benefits of hormones may have changed a little. Over time, these differences between women on active hormones and women on placebo pills look as if they get smaller and may disappear. Right now it seems that the overall risk is no greater than when you started the study. Other studies have shown that the benefits of hormones may take many years to develop.

Your Continued Participation

The WHI Hormone Program is now more important than ever. This new information highlights the critical role you play in finding answers to questions about hormones and women's health. Women and doctors need better information about hormones and their long-term benefits and risks. No other current U.S. study will be able to find the answers. WHI is a landmark study that will provide unique information about women's health. As always, your participation is voluntary.

**We thank you once again for helping us find answers
for generations of women to come!**

