

What about Estrogen-Alone?

Your Important Role in the WHI Hormone Program

All over the world—on television, in magazines and newspapers, at doctors' offices and coffee shops—hormones and women's health are being discussed. Much of that discussion has been prompted by findings from the Estrogen Plus Progestin (E-plus-P) study of the Women's Health Initiative. And the first question raised in those reports and conversations is often, "What about women who are taking estrogen alone, without progestin?" What are the risks and benefits of estrogen in women who have had a hysterectomy? As a WHI VIP (Very Important Participant) in the Estrogen-Alone (E-Alone) study of WHI, you are helping us answer those questions.



Why do I keep hearing news about hormones and WHI?

Studies like WHI are carefully planned to continue only as long as needed to answer the primary questions being asked. The results of the E-plus-P study were released <u>early</u>, because by July 2002 we had answers to our questions about the combination of estrogen plus progestin and women's health. Women in the E-plus-P study continue to provide data about how disease risks and health benefits change after stopping estrogen plus progestin study pills.

As a participant in the Estrogen-Alone study, we ask you to continue to take your study pills and to come in for regular clinic visits. The National Heart, Lung, and Blood Institute, which oversees the WHI, continues to review the study of women receiving estrogen alone and will provide investigators and participants with any new information that might affect their participation.

In order to understand even more about estrogen plus progestin and women's health, data from that study continue to be analyzed and reported. You may have read or heard about new findings from that study. For example:

- ▶ There were no clear quality of life benefits to taking estrogen plus progestin in terms of energy, social functioning, mental health, depression, or sexual satisfaction. There were slight improvements in physical functioning, pain, and sleep in women taking estrogen plus progestin compared to those taking placebo at one year. However, these effects were very small.
- ▶ The WHI Memory Study (WHIMS) released findings on participants who were age 65 and over when they joined. WHIMS participants taking estrogen plus progestin showed a decline in memory and thinking ability compared to those taking placebo. We do not know what these findings mean for younger women or women taking estrogen alone.

You will probably hear about other findings from the E-plus-P study in the future. Data from that study are still being analyzed, and more detailed findings on specific health problems—such as breast cancer, diabetes, endometrial cancer, fractures, heart disease, ovarian cancer, and menopausal symptoms—will be released.

How do these Estrogen Plus Progestin findings apply to women in the Estrogen-Alone Study?

It might be hard to hear about E-plus-P study results and wonder what they mean for you. Some of the news headlines about these findings have been sensationalized. Sometimes the articles use the terms "estrogen" or "hormones" and do not clearly state that the information is only about the estrogen plus progestin combination used in this study.

The findings of the Estrogen-Alone study may not be the same as for the Estrogen plus Progestin study. We will keep you informed of any benefits or risks that might affect your participation in the Estrogen-Alone study.

What if I'm also in the Dietary Study?

The Dietary Study continues as before. We need answers to questions about the role of diet in women's health. Attend your clinic visits just as you always have. If you are in the Dietary Change part of the study, keep coming to sessions too. Participants who are in both the Dietary and E-Alone studies will help us understand more about how the combination of diet and hormones affects postmenopausal women's health and their risk for breast cancer, colorectal cancer, heart disease, and fractures. For example, you will help us learn about the effects of E-Alone and dietary change on the development of breast cancer in women who might be at low or high risk for this disease.

What if I'm also in the Calcium and Vitamin D Program?

The Calcium and Vitamin D (CaD) Program continues as before, because we still need to understand whether calcium and vitamin D supplements decrease a woman's risk of hip and other fractures and cancers of the colon and rectum. Please continue to take your CaD study pills, as you have in the past. We have much more to learn about the combination of CaD and E-Alone from participants, like you, who are in both studies. For example, the information you are providing will help us understand the effects of this combination on bone fractures compared to either therapy by itself.

How can I find out more?

You can find more information about the WHI, E-Alone, and study findings, when they are released, on the WHI web site at www.whi.org. Your WHI clinic staff can also provide you with this information and answer any questions or concerns you may have.

Thank you for your participation in the WHI E-Alone Study!

You are a member of a large community of women across the United States who volunteer their time to the WHI for many different reasons. These reasons are also important to women and their health care providers all over the world, who are waiting for answers to the question, "What about E-Alone?" With your help, we will be able to provide those answers.

