

Participants in the Women's Health Initiative Memory Study (WHIMS) Estrogen-Alone Trial Stop Study Pills and Begin Follow-up Phase

WINSTON-SALEM, N.C., March 2, 2004-- Women participating in the Estrogen-Alone hormone therapy clinical trial of the Women's Health Initiative study were instructed by the National Institutes of Health (NIH) to stop taking their study pills on February 29, 2004 and to begin a follow-up phase of the study. The primary reasons for stopping the trial at this time, 13 months prior to the planned study's end, were:

- An increased risk of stroke
- No apparent protective effect on coronary heart disease

The Women's Health Initiative Memory Study (WHIMS), is an ancillary study to the WHI E-Alone Trial in which women were followed to determine the effects of E-alone as compared to placebo on probable dementia and mild cognitive impairment in women 65 years of age and older. The WHIMS estrogen-alone study involved 2,947 women who had undergone a hysterectomy, were between ages 65-79 at the time the study began, and who completed nearly six years of follow-up at 39 WHI clinical centers throughout the United States. Once the women met the criteria for participation, including screening tests to make sure they did not have dementia at the study's start, they were randomly assigned to take estrogen-alone therapy (one pill per day of conjugated equine estrogen (CEE), 0.625 mg, – brand name PremarinTM) or a look-alike placebo. Cognitive status was evaluated annually, and women with signs of decline were examined in greater depth to further characterize their cognitive status.

At this time, preliminary analyses of the WHIMS data suggest there was no benefit with respect to dementia and a potentially adverse trend with respect to the combined endpoint of dementia and/or mild cognitive impairment for women who were taking Estrogen-alone. Currently, WHIMS investigators, led by the coordinating center located at Wake Forest University School of Medicine, are conducting additional analyses on the WHIMS data. The WHIMS investigators plan to publish the findings in a peer-reviewed scientific journal in Spring 2004. Further information about the WHIMS E-Alone study will not be available until analyses are complete and the paper has undergone full peer-review.

WHIMS was initially funded by Wyeth Pharmaceuticals, manufacturer of Premarin, which provided it for use in the WHI trials. The larger WHI trials are supported by the National Heart, Lung, and Blood Institute (NHLBI) of the NIH. General information on hormone therapy and the Women's Health Initiative can be found on the NIH/WHI website <http://www.nhlbi.nih.gov/whi/index.html>. Further information on the WHIMS study can be found at <http://www.wfubmc.edu/whims>



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