

National Heart, Lung, and Blood Institute

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Contact: NHLBI Communications Office

(301) 496-4236

E-mail: nhlbi_news@nhlbi.nih.gov

Additional Analyses from the Women's Health Initiative

NHLBI Media Availability: Effect of Hormone Therapy on Risk of Heart Disease May Vary by Age and Years Since Menopause

WHAT: Secondary analyses of findings from the Women's Health Initiative (WHI) suggest that women who begin hormone therapy within 10 years of menopause may have less risk of coronary heart disease (CHD) due to hormone therapy than women farther from menopause. Overall, hormone therapy did not reduce the risk of CHD. However, the farther a woman was from the onset of menopause when she began hormone therapy, the greater her risk of CHD due to hormone therapy appeared to be. Although these findings did not meet statistical significance, they suggest that the health consequences of hormone therapy may vary by time from menopause.

These findings are consistent with the primary publications from the WHI trials of estrogen plus progestin and estrogen-alone (total of 27,347 participants) in showing no overall benefit for CHD, and in suggesting that risk due to hormones may differ depending on age or years since menopause.

"Postmenopausal Hormone Therapy and Risk of Cardiovascular Disease by Age and Years Since Menopause," will be published in the April 4 issue of the *Journal of the American Medical Association*.

In a secondary analysis, scientists reanalyze previously collected data and findings in an effort to clarify or ask new questions. In the case of this latest WHI analysis, the authors combined the data from the two trials to explore in more detail the previously observed trends in hormone effects by distance from the menopause. Differences in hormone therapy effects were examined in three age categories (50 to 59, 60 to 69, and 70 to 79) or in years since the onset of menopause (less than 10, 10 to 19, and 20 or more). The Women's Health Initiative and the newly published analyses are funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health.

The analyses also suggest that the increased risk in heart disease due to hormone therapy in older women is primarily in those who also have hot flashes and night sweats. Study participants who had these symptoms were more likely to have risk factors for CHD such as high blood pressure or high blood cholesterol, but it was not clear whether this explained their higher risk on hormone therapy.

Other results from the analyses of the combined trials include:

- ✓ Confirmation that hormone therapy increases the risk of stroke and this risk does not appear to be influenced by age or time since menopause
- ✓ Even in women within 10 years of menopause, there appears to be an increased risk of breast cancer in women taking estrogen with a progestin
- ✓ There was a trend (not statistically significant) towards reduced risk for death associated with hormone use in younger compared to older women.

WHI is a major 15-year research program designed to address the most frequent causes of death, disability and poor quality of life in postmenopausal women -- cardiovascular disease, cancer, and osteoporosis. Both the estrogen plus progestin and estrogen-alone trials of the WHI were stopped early because of increased health risks and the failure to prevent heart disease. Specifically, the estrogen plus progestin trial was stopped after 5.6 years because of an increased risk of breast cancer and because overall risks, including increased risks for heart attack, stroke, and blood clots, outnumbered benefits. The estrogen-alone study was stopped after 6.8 years because of an increased risk of stroke and no reduction in risk of CHD. The estrogen-alone study also found an increased risk of blood clots.

WHO: Jacques Rossouw, M.D. chief of the Women's Health Initiative Branch at NHLBI, and lead author of the study, is available to comment on the implications of the new study for women considering hormone therapy at different ages. He will note that the findings may be somewhat reassuring to younger women considering hormone therapy for short term relief of symptoms, but do not change the current recommendation that hormone therapy should not be used at any age for prevention of CHD. Women considering hormone therapy should have risk factors such as blood pressure and blood cholesterol measured and managed, and have regular mammograms. Dr. Rossouw can comment on the need for additional research to explore the overall findings and the finding regarding night sweats and hot flashes.

CONTACT: To schedule interviews with Dr. Rossouw, contact the NHLBI Communications Office at 301-496-4236 or e-mail nhlbi_news@nhlbi.nih.gov

Part of the National Institutes of Health, the National Heart, Lung, and Blood Institute (NHLBI) plans, conducts, and supports research related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases; and sleep disorders. The Institute also administers national health education campaigns on women and heart disease, healthy weight for children, and other topics. NHLBI press releases and other materials are available online at: www.nhlbi.nih.gov.

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