



Press Release

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KEEPS: Archives of Internal Medicine Analysis Indicates Younger Women May Receive Heart Protection from Estrogen Therapy

Study Suggests More Research Is Needed on Younger Women

PHOENIX (Feb. 13, 2006) – An analysis from the Women’s Health Initiative published in the current issue of *Archives of Internal Medicine* (“Conjugated Equine Estrogens and Coronary Heart Disease”) suggests that younger menopausal women, ages 50-59, may receive cardiac protection from estrogen therapy. It also demonstrates that older women do not have heart benefits from estrogen therapy.

“This study further emphasizes the need for additional research on a younger group of women who are recently menopausal,” said Dr. S. Mitchell Harman, director and president of Phoenix-based Kronos Longevity Research Institute (KLRI), a nonprofit that is spearheading the Kronos Early Estrogen Prevention Study (KEEPS). “Because the women in the WHI estrogen-only trial were older, with a mean age of 63.6, there are limited data on younger women for doctors to work with.”

Dr. JoAnn Manson, a WHI and KEEPS principal investigator and co-author of the *Archives of Internal Medicine* analysis, emphasized that hormone therapy (HT) should not be used for the express purpose of preventing heart disease. She added, “However, these findings may reassure younger women experiencing moderate-to-severe hot flashes or other menopausal symptoms that HT may be a viable option for them.”

Key findings from the new WHI analysis include:

- In women ages 50-59 who had undergone a hysterectomy, a significant protective effect of estrogen treatment, when both primary (heart attacks and heart attack death) and secondary (coronary artery bypass surgery, angioplasty, confirmed angina pectoris) cardiac endpoints were considered.
- In women of all ages, significant effects of estrogen on intermediate blood markers, including LDL cholesterol, glucose and insulin. Insulin, glucose and LDL cholesterol levels were significantly reduced; HDL cholesterol levels were significantly increased. However, triglycerides (a “bad” fat) were also significantly increased.
- There was significantly greater use of statin (cholesterol lowering) drugs in the placebo

group over the course of the study, but adjusting for effects of statin use did not alter overall results.

“These findings are consistent with earlier observational studies and with our hypothesis that estrogen may be good early and bad late,” Dr. Harman said. “KEEPS has been designed to provide useful new data to begin answering women’s questions and to help shape future research.”

HORMONE THERAPY

About KEEPS

Eight national study centers are currently recruiting for KEEPS, which is being coordinated and sponsored by KLRI. KEEPS is a randomized, controlled, double-blind trial of 720 women, designed to provide prospective data on the risks and benefits of HT in recently menopausal women, particularly as it relates to the progression of hardening of the arteries (atherosclerosis). The results of the Women’s Health Initiative (WHI) estrogen plus progestin trial, which was halted by the National Institutes of Health in July 2002, prompted a consortium of health researchers to study the risks and benefits of HT on a younger subset of women who recently entered menopause. Prior to the WHI, most data suggested HT was associated with a high degree of protection (30 to 50 percent reductions) against coronary heart disease, all-cause mortality and osteoporotic fractures, in addition to a small increase in breast cancer risk. Recent studies in the Journal of Women’s Health and the Archives of Internal Medicine indicate that HT may indeed provide coronary heart protection if given to recently menopausal women.

The participants are being divided into three groups. The first group is receiving an oral tablet containing low dose conjugated equine estrogens (Premarin , 0.45 mg daily) and a placebo (inactive) skin patch. The second group is receiving an oral placebo tablet and a skin patch delivering low dose estradiol (Climara , 0.50 mcg/day). The third group (control) is receiving a placebo tablet and a placebo skin patch. Women receiving active estrogen also will take progesterone capsules (Prometrium , 200 mg daily for first 12 days of each month) to protect the uterine lining from overgrowth. Subjects not receiving active estrogens will take placebo capsules. The study will last four years. In addition to the imaging studies above, the effects of HT on quality of life and memory/cognitive function will be assessed.

About KLRI

KLRI is a not-for-profit 501 (c) (3) organization that conducts state-of-the-art clinical translational research on the prevention of age-related diseases and the extension of healthier human life. Translational research is the critical link between findings from the basic research laboratory and corresponding improvements in clinical care. In addition to KEEPS, KLRI currently is studying Testosterone Effects on Atherosclerosis in Aging Men (TEAAM Study). For more information on KEEPS, visit KLRI’s Web site at www.keepstudy.org or call 1(866) 878-1221.

Center Contacts

For recruitment information relative to a specific center, please contact the following individuals:

- Albert Einstein College of Medicine/Montefiore Medical Center (New York City): Barbara Issac, (718) 430-3152
- Brigham and Women’s Hospital/Harvard Medical School (Boston): Kate Kalan, (617) 732-9870

- Columbia University College of Physicians and Surgeons (New York City): Amber Ahmad,
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- Mayo Clinic College of Medicine (Rochester, MN): Teresa G. Zais, (877) 323-5337
- University of California, San Francisco Medical Center/Women's Health Clinical Research Center: Nancy Jancar, (415) 353-4300
- University of Utah School of Medicine (Salt Lake City): Stacey Larrinaga-Shum, (801) 585-0374
- University of Washington School of Medicine (Seattle): Colleen Carney, (253) 583-2040
- Yale University School of Medicine (New Haven, CT): Diane Wall, (203) 785-4739

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