

Extended follow-up of hormone therapy trials does not support use for chronic disease prevention

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Extended follow-up of the two Women's Health Initiative hormone therapy trials does not support use of hormones for chronic disease prevention, although the treatment may be appropriate for menopausal symptom management in some women, according to a study in the October 2 issue of *JAMA*.

The hormone therapy trials of the Women's Health Initiative (WHI) were stopped after investigators found that the [health](#) risks outweighed the benefits. Menopausal hormone therapy continues in clinical use, but questions remain regarding its risks and benefits over the long-term for chronic disease prevention, according to background information in the article.

JoAnn E. Manson, M.D., Dr.P.H., of Brigham and Women's Hospital, Boston, and colleagues provide a comprehensive, integrated overview of findings from the two WHI hormone therapy trials with extended post-intervention follow-up and stratification by age and other important variables. The study included 27,347 postmenopausal women, ages 50 through 79 years, who were enrolled at 40 U.S. centers in 1993. Women with an intact uterus received conjugated equine estrogens (CEE) plus medroxyprogesterone acetate (MPA) (n = 8,506) or placebo (n = 8,102). Women with prior hysterectomy received CEE alone (n = 5,310) or placebo (n = 5,429). The intervention lasted a median [midpoint] of 5.6 years in the CEE plus MPA trial, and 7.2 years in the CEE alone trial,

with 6-8 additional years of follow-up until September 30, 2010.

The researchers found that overall, the risks of CEE+MPA during intervention outweighed the benefits. Risks were increased for [coronary heart disease](#), [breast cancer](#), stroke, pulmonary embolism, dementia (in women 65 years of age and older), gallbladder disease, and urinary incontinence. Benefits included decreased hip fractures, diabetes, and vasomotor symptoms. Most risks and benefits dissipated postintervention, although some elevation in breast cancer risk persisted during follow-up.

For CEE in women with prior hysterectomy, the benefits and risks during the intervention phase were more balanced, with increased risks of stroke and venous thrombosis, reduced risk of hip and total fractures, and a nonsignificant reduction in breast cancer. Post-intervention with CEE, a significant decrease in breast cancer emerged and most other outcomes were neutral. For CEE alone, younger women (age 50-59 years) had more favorable results for all-cause death and heart attack.

Neither regimen affected all-cause mortality.

"In summary, current WHI findings based on results from the intervention, postintervention, and cumulative posttrial stopping phases do not support the use of either estrogen-progestin or estrogen alone for chronic disease prevention," the authors write.

"Even though hormone therapy may be a reasonable option for management of moderate to severe menopausal symptoms among generally healthy women during early menopause, the risks associated with hormone therapy, in conjunction with the multiple testing limitations attending subgroup analyses, preclude a recommendation in support of CEE use for [disease prevention](#) even among younger women. Current findings also suggest caution when considering hormone therapy

treatment in older age groups, even in the presence of persistent [vasomotor symptoms](#), given the high risk of coronary heart disease and other outcomes associated with hormone therapy use in this setting."

"Twenty-two years following its inception, the WHI is a model for publicly funded rigorous, thorough, and objective clinical trials that have broadly affected human health. More than 160,000 women participated (many with great pride), more than 900 peer-reviewed reports from the WHI Publications and Presentations Committee have been published, the WHI data set is publically available, and scores of trainees have been mentored in fields from human biology to public health by participating in its analysis. The WHI has overturned medical dogma regarding the use of menopausal [hormone therapy](#)," writes Elizabeth G. Nabel, M.D., of Brigham and Women's Hospital, Boston, in an accompanying editorial.

"The WHI underscores the decisive importance of taxpayer-funded research conducted by the National Institutes of Health (NIH). Further reductions in the NIH budget virtually ensure that vitally important studies like the WHI will not be conducted, and hence, U.S. society will be poorly served. The fact that the public sector undertook this historic project (and that the researchers whose work is now reported have taken it to its next stage) has moved medical science forward by the most effective means of doing so—shattering prior dogma. For that, [women](#) and all patients whose health depends on sound science are grateful."

More information: [DOI: 10.1001/jama.2013.278040](https://doi.org/10.1001/jama.2013.278040)
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