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# The KEEPS Trial: Hormone Therapy Has Many Favorable Effects in Newly Menopausal Women

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Oct 04, 2012

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Hello. This is Dr. JoAnn Manson, Professor of Medicine at Harvard Medical School and Brigham and Women's Hospital. I am also the current President of the North American Menopause Society (NAMS).

I would like to talk with you about some new and exciting findings from the [KEEPS \(Kronos Early Estrogen Prevention Study\) trial](#), which were presented for the very first time at the [NAMS 23rd Annual Meeting](#) this week.<sup>[1]</sup>

The primary results of the KEEPS trial were presented during a plenary symposium by Drs. Mitchell Harman, Sanjay Asthana, and myself. The plenary symposium, together with the summary of the trial results, will be posted on the [NAMS Web site](#) next week. I am going to highlight a few of the key findings of the trial.

The KEEPS trial included 727 women who were newly menopausal, within 3 years of the onset of menopause, and had an average age of 52.7 years. The trial tested 2 different types of estrogen compared with placebo: a low-dose oral conjugated estrogen at a dose of 0.45 mg/day, and a transdermal estradiol patch at a dose of 50 µg/day. Both [forms of estrogen were taken] with cyclic micronized progesterone (Prometrium®, Abbott Laboratories) for 12 days per month.

The trial was not large enough to assess effects on clinical outcomes, such as heart attacks and strokes, but it focused on quality-of-life parameters, noninvasive imaging of atherosclerosis of the carotid and coronary arteries, cardiovascular risk-factor changes and biomarkers, cognitive function, mammographic breast density, and several other outcomes.

Overall, the KEEPS trial showed many favorable effects of hormone therapy. A substantial reduction in menopausal symptoms (hot flashes, night sweats) and also some improvement in bone mineral density [were seen in the active treatment groups] compared with the placebo group.

In terms of blood pressure, the effect was neutral. Systolic blood pressure was not increased as had been seen with the conventional dose of estrogen used in the Women's Health Initiative (WHI) trial.<sup>[2]</sup>

In terms of lipids, oral conjugated estrogen showed a reduction in LDL cholesterol and an increase in HDL cholesterol, but also an increase in triglyceride levels, likely related to first-pass metabolism in the liver. In contrast, transdermal estradiol had a relatively neutral effect on lipids. Transdermal estradiol had a favorable effect on insulin resistance as measured by HOMA-IR (Homeostatic Model Assessment of Insulin Resistance) from glucose and insulin levels.

With noninvasive imaging of the carotid and coronary arteries, very little progression of atherosclerosis was observed in this young, newly menopausal study population. As a result, it was not possible to see significant differences between the hormone therapy arms and the placebo arm, although with coronary artery calcium, a trend of less development of coronary artery calcification was suggested in women who were assigned to take estrogen compared with women who were taking the placebo. It will be necessary to have longer-term follow-up of the study population to see if differences occur as the women get older and [over a longer period of time].

In terms of cognitive function, no adverse effect was seen -- a neutral effect -- in contrast to the deleterious effect that was seen with hormone therapy in the WHI study in women aged 65 years and older.

In terms of mammographic density and the need for additional testing and follow-up mammography, [the results of the trial] suggested that the women on oral conjugated estrogen may have needed less follow-up testing than those on transdermal estrogen. But these are preliminary findings, and you will be hearing more about these findings in the future.

In terms of mood and sexual function, evidence for benefits [for both outcomes] and also quality of life were seen with both forms of hormone therapy.

Overall, in summary, many favorable effects of hormone therapy were seen in these recently menopausal women. The women with symptoms appeared to have quality-of-life benefit and an overall favorable benefit:risk ratio. The findings really underscore the need for individualized decision-making about hormone therapy in women, because the decision about starting hormone therapy and the choice of type of hormone therapy will depend on a woman's underlying risk factor status, her various symptoms, and her priorities for treatment.

Thank you very much for your attention. This is Dr. JoAnn Manson.

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