

**Contacts:**

Brian Edelstein, Account Manager
McKinney Advertising & Public Relations
Cleveland, OH
Phone: (216) 621-5133 / Fax: (216) 621-1181
E-mail: bedelstein@mckinneyad.com

THE NORTH AMERICAN MENOPAUSE SOCIETY ISSUES INITIAL REACTION TO TERMINATION OF ESTROGEN-ONLY ARM OF THE WOMEN'S HEALTH INITIATIVE

CLEVELAND (March 2, 2004) — Participants in the estrogen-only arm of the Women's Health Initiative (WHI) have been instructed to discontinue taking their study medication and to begin the follow-up phase of the study, according to the National Institutes of Health (NIH), the study sponsor. The estrogen-only arm was terminated before its planned completion in 2005 based on an analysis of the data showing that estrogen alone does not appear to either increase or decrease the risk of heart disease, a key end point of the study. Furthermore, estrogen did increase the risk of stroke, which the NIH stated is unacceptable in healthy women in a research study, especially given the lack of improvement in heart disease risk. The NIH also determined that with 7 years of data already collected, the results would not be likely to change if the estrogen-only arm were continued. Other results showed that estrogen alone decreased the risk of hip fracture, and it did not increase the risk of breast cancer.

“This is an important announcement from the NIH,” said Wulf H. Utian, MD, PhD, Executive Director of The North American Menopause Society (NAMS). “The announced reason for termination of the estrogen-only arm is a slight increase in risk for one adverse effect (stroke), but otherwise, it appears to be reassuring regarding estrogen-only use. It is not clear whether the increase in stroke risk applied to all women studied or only those aged 65 and older.”

Location

5900 Landerbrook Drive
Suite 195
Mayfield Heights, OH 44124

Mailing Address

Post Office Box 94527
Cleveland, OH 44101-4527

Telephone: 440/442-7550

Fax: 440/442-2660

E-Mail: info@menopause.org

Web Site: www.menopause.org

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“Until the full information is published, and this is anticipated in mid-April, the current recommendation from NAMS is that there is no urgent need to change any clinical practice. The statements in the NAMS September 2003 Position Statement on estrogen and progestogen use in peri- and postmenopausal women remain valid. After the full report is published, further recommendations will follow.” (The NAMS Position Statement can be viewed at <http://www.menopause.org/HTpositionstatement.pdf>.)

Although specific details regarding the increased risk were not provided, the NIH noted that they are similar to those found with the estrogen-progestogen arm of the WHI, which was stopped in July 2002. In that study, women taking estrogen plus progestin had eight more strokes per 10,000 women per year than placebo recipients. The WHI investigators are preparing a detailed data analysis that will include results collected through February 2004. It will be published in a peer-reviewed medical journal within 2 months.

The WHI estrogen-only study was designed to assess the effect of long-term use of hormone therapy in healthy postmenopausal women on the risk of heart disease and hip fractures as well as associated adverse effects, especially breast cancer risk. It was not designed to evaluate short-term risks and benefits, such as treatment of moderate to severe hot flashes. Approximately 11,000 postmenopausal women aged 50 to 79 years who have had a hysterectomy were participating in the estrogen-only arm of the WHI.

NAMS is North America’s leading nonprofit organization dedicated to promoting women’s health during midlife and beyond through an understanding of menopause. The Society’s unique multidisciplinary membership of more than 2,000 healthcare professionals includes experts from medicine, nursing, sociology, psychology, anthropology, pharmacy, epidemiology, nutrition, education, and basic science — helping NAMS to be the preeminent resource on all aspects of menopause to healthcare providers and the public. Its multidisciplinary membership of menopause experts also makes NAMS uniquely qualified to provide menopause-related information that is accurate, well-balanced, and presented without bias. For more Society information, contact the NAMS Central office at (440) 442-7550 or visit the NAMS Web site (www.menopause.org).

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