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Estrogen Study Ends Early and With Mixed Results

In February 2004, the National Institutes of Health (NIH) asked women participating in the estrogen-only arm of the Women's Health Initiative estrogen study to stop taking their study pills.

The study was designed to assess the effects of long-term use of hormone therapy in healthy postmenopausal women on the prevention of heart disease and hip fractures and any associated change in risk for breast cancer. After evaluating nearly seven years of follow-up data, NIH has concluded that estrogen alone does not appear to affect (either increase or decrease) heart disease. It does appear to decrease the risk of hip fracture. However, the study also found that estrogen appears to slightly increase the risk of stroke, which NIH found to be unacceptable for healthy women in a research study.

A total of 11,000 women aged 50–79 who have had a hysterectomy participated in the estrogen-only arm. They were randomized to receive either 0.625 mg per day of conjugated equine estrogen or placebo. An estrogen and progestin arm of the trial also was conducted but was stopped in 2002 after 5.6 years of follow-up because of an increased risk of breast cancer, coronary heart disease, stroke, and blood clots, which outweighed the benefits estrogen and progestin had in preventing hip fractures and colorectal cancer.

Full results from the study were reported in the April 14 issue of the *Journal of the American Medical Association* (Vol. 291, pp. 1701–1712). A separate report will contain information about the Women's Health Initiative Memory Study, which found that women aged 65 and older who took estrogen alone had an increased risk of probable dementia and/or mild cognitive impairment.

Women Treated With Radiation May Have High-Risk Pregnancies

Can cancer survivors become pregnant safely? That is a question that researchers in the Childhood Cancer Survivor Study asked recently, and they discovered that women who have had radiation therapy, especially to the pelvis, are at high risk for pregnancy complications. The study followed 1,915 women with 4,029 pregnancies and found that babies of patients who received pelvic irradiation were more likely to have low birth weights (less than 2,500 g). No adverse pregnancy outcomes were identified for survivors who had received chemotherapy treatment.

Results from a similar study that were presented at a 2003 meeting of the American College of Obstetricians and Gynecologists echoed these findings. This study, which involved 49 cancer survivors and their 63 pregnancies, found that babies of patients who had been exposed to radiation therapy weighed 400 g less than average. Eight preterm babies were born during the study, and five of these babies were delivered to mothers who had received radiation therapy. One mother had prior thoracic radiation and experienced shortness of breath during her pregnancy. She was found to have mitral regurgitation. A second mother had prior thoracic and abdominal radiation, and she was found to have congestive heart failure, aortic regurgitation, intrauterine growth restriction, and severe preeclampsia at 25.5 weeks. Again, women in this study who had received chemotherapy experienced no complications.

Although these studies did not find any association between chemotherapy treatment and pregnancy complications, researchers know that the chemotherapy drug doxorubicin can damage the heart muscle and possibly cause congestive heart failure in the future. Researchers say that women who were treated with doxorubicin should have their cardiac function assessed before and during pregnancy.

New Drug Works With Antiemetics to Control Acute and Delayed Nausea and Vomiting

A new drug, aprepitant (Emend®, Merck & Co., Inc., Whitehouse Station, NJ), which works with other antiemetics to reduce chemotherapy-induced nausea and vomiting, has helped to reduce these symptoms by nearly 50%, according to the results of two studies.

An international phase III trial involved 520 patients with respiratory cancers who received cisplatin. Twenty-six percent of the patients reported nausea and vomiting after receiving aprepitant in addition to ondansetron and dexamethasone (standard treatment); 48% reported the symptoms after receiving placebo with the standard drugs.

A phase II study of aprepitant in the Netherlands found that patients benefited from the drug even after several rounds of chemotherapy. After six cycles of cisplatin, 59% of patients who received aprepitant in addition to standard treatment did not have nausea and vomiting compared to 34% who received placebo.

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