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The Breast Cancer Prevention Trial

This article, authored by the headquarters staff of the National Surgical Adjuvant Breast and Bowel Project (NSABP), provides an overview of the upcoming tamoxifen trial. It discusses the justification for the trial, eligibility criteria, and it provides contacts for patient referral information.

On May 15, 1992, the National Surgical Adjuvant Breast and Bowel Project (NSABP) will begin to randomize 16,000 women in the Breast Cancer Prevention Trial, P-1. A total of 270 sites, representing 45 states, the District of Columbia, and six Canadian provinces will participate in this trial. One-third of the centers are CCOP participants. The trial is being funded by the National Cancer Institute's (NCI's) Division of Cancer Prevention and Control. Additional support will be provided by the National Institute of Heart, Lung, and Blood, and the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

The objectives of the trial are to determine if tamoxifen is effective in 1) reducing the incidence of invasive breast cancer, 2) reducing breast cancer mortality, 3) reducing deaths from cardiovascular disease, and 4) reducing bone fractures. In addition, the study will evaluate side effects, toxicity, and the quality of life of all participants in the study.

Justification for the Trial

Any strategy to prevent breast cancer in otherwise healthy women must have several prerequisites. There should be strong laboratory evidence to indicate the drug's effectiveness in preventing breast cancer. Ideally, it will be effective in the clinical setting. It is important that the drug will be safe, especially for women who will receive the therapy, but are not likely to develop the disease in their lifetime. Tamoxifen, a non-steroidal antiestrogen, is the most widely prescribed antineoplastic agent in the United States that has been used successfully to treat all stages of breast cancer. Trials have demonstrated the benefit from tamoxifen in reducing tumor recurrence and prolonging survival when the drug is used as a single agent, in combination with chemotherapy for the treatment of advanced breast cancer, and as post-operative adjuvant therapy in stage I and II disease. Of particular importance is the observation that patients receiving tamoxifen have a significantly lower incidence of contralateral breast cancer than patients who receive a placebo. Moreover, extensive information indicates that tamoxifen can be administered to women safely, with good compliance, and minimal side effects.

While tamoxifen acts as an antiestrogen in breast tissue, research suggests that it acts like an estrogen in other parts of the body. Evidence has indicated that tamoxifen perturbs lipid and lipoprotein metabolism. As a result, tamoxifen may decrease mortality rates from myocardial infarction. A significant reduction in deaths from acute myocardial infarction was noted in a Scottish trial comparing tamoxifen to no treatment in women with breast cancer.* Further studies have found that tamoxifen stabilizes bone density and, thus, it may also reduce the risk of osteoporosis in women who receive it.**

Eligibility Criteria

Sixteen thousand women in the United States and Canada will participate in this trial. Women 35 to 59 years of age, whose risk for developing breast cancer is at least as great as that of a woman who is 60 years of age, will be eligible. All women 60 years of age or older are eligible to participate by virtue of their age alone; however, both groups of women must meet other eligibility requirements relating to previous health problems and life expectancy. Women of the ages 35 to 59 will have their risk for breast cancer and eligibility evaluated through the use of a computerized model. That model is based on the following risk factors: number of first degree relatives with breast cancer (mother, sisters or daughters); a personal history of lobular carcinoma in situ; history of atypical hyperplasia; history of previous breast biopsies; nulliparity; age at first live birth; and age of menarche. Lifetime probabilities for developing breast cancer will be estimated for each potential participant.

Prior to entry, the participant must have a normal physical examination, including a breast and gynecologic examination. Baseline laboratory tests and mammograms will also be required. The 16,000 women who are enrolled in the trial will be randomized into two groups. One group will receive 20 milligrams of tamoxifen daily for five years, and the other group will receive a placebo for five years. All women in the trial will obtain periodic medical examinations, including a yearly mammogram and gynecologic exam, throughout the duration of the trial.

Summary

Tamoxifen is one of the most commonly prescribed drugs for cancer in the world. There is extensive knowledge about its benefits, side effects, and toxicities. Both laboratory tests and clinical evidence suggest that it will reduce the number of new breast cancers. We do not know that for a fact. The way to determine its effectiveness in preventing breast cancer is to perform a well designed, randomized clinical trial. At present, there is no justification for using tamoxifen to prevent breast cancer outside of a clinical trial.

Physicians who are interested in referring potential participants may contact the NCI's Cancer Information Service (800/4-CANCER) for the nearest participating center. The NCI's PDQ listing also contains referral information. In Canada, centers participating in the study can be located through several organizations: British Columbia and the Yukon (604/879-2323); Ontario (800/263-6750); Quebec (800/361-4212); and other regions (416-387-1153). ■

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* McDonald, C. C., Stewart, H. J. Adjuvant Tamoxifen in the Management of Early Breast Cancer: The Scottish Trial. Breast Cancer Trials Committee, Scottish Cancer Trials Office. *Lancet* 1987:2, 171–175.

** Love, R. R., Mazess, R. B., et al. Effects of Tamoxifen on Bone Mineral Density in Postmenopausal Women with Breast Cancer. *N. Eng. J. Med.* 1992: 326, 852–856.