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National Surgical Adjuvant Breast and Bowel Project

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CONTACT
Lori Garvey
NSABP Operations Center
(412) 330-4621

FEWER WOMEN NEEDED TO DETERMINE RESULTS OF BREAST CANCER PREVENTION STUDY

Pittsburgh, PA -- The Study of Tamoxifen and Raloxifene (STAR), a study to determine whether or not raloxifene can prevent breast cancer better and with fewer side effects than tamoxifen, began recruiting 22,000 postmenopausal women in July 1999.

Today, researchers from the National Surgical Adjuvant Breast and Bowel Project (NSABP), the group conducting the trial, announced that the National Cancer Institute (NCI) funded study can be completed with fewer women—only 19,000 will be needed.

The original estimate of the number of the women needed for the study was based on volunteers having at least a 1.7 percent chance of developing invasive breast cancer within five years—about 17 women per 1,000. But STAR enrollees to date have had about twice the minimum risk, or a 3.5 percent chance of developing cancer within that time period—35 per 1,000 women. This greater risk means that fewer women are required to see prevention effects from the drugs. The researchers hope to complete enrollment next summer; study results may be available by 2006.

STAR is the follow-up study to the landmark Breast Cancer Prevention Trial (BCPT), published in 1998, that led to tamoxifen being approved by the U.S. Food and Drug Administration for risk reduction in women at increased risk for developing breast cancer. Thus far, over 17,000 women at more than 500 sites in the United States, Canada, and Puerto Rico have volunteered for STAR. The trial is endorsed by the American Cancer Society.

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"When designing the trial and calculating the number of participants we would need, we estimated that most women would have a certain increased likelihood of developing breast cancer," explained Norman Wolmark, M.D., chairman of the NSABP and of the Department of Human Oncology at Allegheny General Hospital in Pittsburgh, Pa. "But the women who are entering the study have a much greater chance of developing breast cancer based on known risk factors."

"Because the participants are more likely to develop cancer than women at a lesser risk of the disease, the study will be able to get answers with fewer volunteers," Wolmark said. "The other important factor is that so many of the women who have already volunteered are really committed to the trial. In any clinical trial, participants can withdraw at any time, for any reason. Fortunately, in STAR we have a strong core of dedicated volunteers, and we are certain we'll be able to obtain our answers with 19,000 women."

"NCI is pleased that STAR will be able to reach its conclusions with 3,000 fewer women than we originally planned," said Leslie Ford, M.D., associate director for clinical research in NCI's Division of Cancer Prevention. "We will do everything we can to make sure enrollment efforts continue at their current pace, so we can reach our goals on time or ahead of schedule."

"I am a huge supporter of breast cancer prevention trials," said Judith Jordan, chair of STAR's Participant Advisory Board, a group of eighteen study participants who represent the women in the trial. "I participated in the first Breast Cancer Prevention Trial and after finding out that I was in the placebo group, I immediately decided to join STAR. The way I see it, this is a win-win situation."

Jordan continued, "Even if women are not interested in joining a study, I would strongly encourage them to visit a new NSABP Web site, www.breastcancerprevention.com where they can determine their personal risk for developing breast cancer. It is good information to have. Knowledge is power."

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The Web site has a computerized formula, known as the Gail model, that allows a woman to estimate her risk of developing breast cancer in the next five years and in her lifetime. The model uses factors such as age, family history of breast cancer, and other personal individual factors to determine these estimates. Most importantly, the Gail model, developed by researchers at the NCI and the NSABP, has been scientifically analyzed and found to be reliable.

"In my experience, I find that women tend to overestimate their breast cancer risk, leading to increased anxiety about developing the disease," said Ford. "Information that women get about their personal breast cancer risk from the Web site will allow them to have a conversation with their doctor to map a strategy for good breast care. One option for women who find that they are at increased risk is the STAR study."

STAR includes postmenopausal women who are at increased risk for breast cancer due to a combination of factors such as age, family history of breast cancer, personal medical history, age at first menstrual period, and age at first live birth. Once a woman chooses to participate she will be randomly assigned to take other either tamoxifen (Nolvadex®) or raloxifene (HCL) (Evista®) daily for five years and will have regular follow-up examinations. The maker of tamoxifen, AstraZeneca Pharmaceuticals, Wilmington, Del., and the maker of raloxifene, Eli Lilly and Company, Indianapolis, Ind., are providing their drugs for the trial without charge.

For more information about STAR and to locate a list of participating sites, contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237). The number for callers with TTY equipment is 1-800-332-8615. In Canada, call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333. You may also visit http://www.breastcancerprevention.com for detailed information.

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