NSABP

Constellation

A Newsletter for All STAR Participants

Winter 2002/2003
Volume 3, Issue 1

STAR
Study of Tamoxifen And Raloxifene

The Rise & Fall of Hormones

What Every Woman Should Know About Hormone Replacement Therapy

Victor G. Vogel, MD, MHS, STAR Protocol Chair

Victor G. Vogel, MD, MHS is the Professor of Medicine and Epidemiology and Director at Magee-Womens Hospital/University of Pittsburgh Cancer Institute Breast Program. His research interests in breast cancer risk assessment and prevention has prompted numerous honors and awards from many organizations including the United States Public Health Service, the Susan G. Komen Breast Cancer Foundation, and the American Cancer Society, among others. Along with his duties as the STAR protocol chair, a position that helps to guide the study, he is involved with numerous boards and committees including the Data and Safety Monitoring Board, an independent review board that oversees the Women's Health Initiative (WHI) of the National Institutes of Health (NIH). He has authored more than 150 articles, book chapters, and abstracts, and edited the book "Management of Patients at High Risk for Breast Cancer" (Blackwell Science 2001).

Does the use of oral contraceptives increase breast cancer risk?

The available data indicate that among current users of oral contraceptives, there is a 20%-30% increase in the risk of breast cancer (indicated by a relative risk greater than 1.0). When a woman stops taking oral contraceptives, her breast cancer risk begins to fall. After 5-10 years have elapsed since the last use of oral contraceptives, there is no apparent increased risk of developing breast cancer.[1]

These data were generated from women who used oral contraceptive pills in the 1960s and 1970s that contained higher amounts of estrogen than today's oral contraceptives. Therefore, these data may not apply to women using the current preparations.

Does the use of hormone replacement therapy (HRT) increase breast cancer risk?

Yes, results from multiple analyses indicate that the risk of developing breast cancer is elevated in women who are current users of HRT, and that the risk increases with cumulative months of HRT use.[2, 3, 12] The Women's Health Initiative's estrogen plus progestin arm showed that women taking HRT have a 25%-30% increased risk of developing breast cancer, or for every 10,000 women on HRT per year there will be eight more invasive breast cancers as compared to women taking placebo.[4]

Does the risk of dying from breast cancer increase with HRT use?

Some of the published studies and analyses suggest that cancers diagnosed in women who have used HRT, either at the time of diagnosis or previously, are less clinically advanced than those in women who have never used HRT. These studies also indicate that HRT use probably does not increase the risk of dying from breast cancer.[2, 3] The Puget Sound Group Health Cooperative published data from a matched case-control study of 2,755 women showing that recurrence and mortality rates were reduced in women who used HRT after diagnosis of breast cancer.[6] There are, however, conflicting results, and no large meta-analyses have evaluated HRT use and breast cancer mortality.[12]

Will the increased risk of breast cancer associated with HRT stop after discontinuation of HRT?

The Nurses' Health Study found that there is no increase in the risk of breast cancer for women who are past users of HRT, regardless of duration of use.[2] While a reanalysis of the results from fifty-one epidemiological studies indicate that the increased risk associated with HRT is reduced after discontinuation of HRT, and has largely disappeared after five years of non-use.[3]

What are the effects of HRT on the cardiovascular system?

The Heart Estrogen Replacement Study (HERS) evaluated the effect of HRT on coronary heart disease (CHD) events in postmenopausal women with established coronary disease. Contrary to the earlier findings of observational studies, results from HERS (a placebo-controlled study) showed that HRT did not

...Continued on page 4

Co-STAR

STAR Sub-Study on Memory, Mood, and Sleep Habits Seeks Participants Age 65 and Older

Co-STAR (**CO**gnition in the **S**tudy of **T**amoxifen **A**nd **R**aloxifene), a substudy of STAR trial, is recruiting women who are age 65 or older and who have been enrolled in STAR for at least one year. As reported in the Spring 2002 edition of *Constellation* (Volume 2, Issue 1), Co-STAR is a research study examining the possible effects of tamoxifen and raloxifene on memory, mood, and sleep in age-appropriate women.

As women age, they often have concerns about declines in memory. Women are also interested in how medications and other life choices might prevent such declines. A Co-STAR participant from Minnesota decided to participate in Co-STAR because, "I'm a curious person and a concerned person wondering if the changes I think I'm having as I get older could be helped or stopped by a drug."

Studies suggest that hormone replacement therapy (HRT) might prevent declines in memory and thinking in aging women. At this time, it is unknown whether tamoxifen and raloxifene might also prevent these changes. The Co-STAR study is designed to answer these questions.

Why Should I Participate?

By participating in the Co-STAR study, you will ultimately be joining 1,800 women across the United States and Canada with similar concerns about memory. You will be helping others, including physicians and other health care professionals to have a better understanding of the effects of tamoxifen and raloxifene on memory and thinking. This could alter the future health care of women in your family, community, and around the world.

James N. Atkins, M.D., the STAR principal investigator for the Southeast Cancer Control Consortium (Winston-Salem, North Carolina) –whose site has successfully recruited the largest number of Co-STAR participants to date– states "every woman that we see in the office today is benefitting from the research of yesterday. Likewise, the women who are participating in STAR and Co-STAR may not directly benefit from their efforts now, however their children and grandchildren may and that keeps hope alive." Dr. Atkins continues, "our Co-STAR participants are going above and beyond their STAR commitments to help us better understand the possible effects that tamoxifen and raloxifene may have on memory and thinking and for that they should be commended. We would like to see others join this quest and encourage all STAR participants to talk to their program coordinators about Co-STAR."

Here's what some Co-STAR participants are saying:

- *"I decided to do it (join the Co-STAR study) thinking that it might help others some day. I have a few memory problems myself, and maybe what they find out will help others have none."*
  – **Co-STAR participant, Minnesota**
- *"If you feel the need to help, think of those that it will benefit in the future (daughters, granddaughters)."*
  – **Co-STAR participant, South Carolina**

...Continued on page 2

Inside This Issue

STAR Enrollment Report

~~22,000~~
19,000 Sample size being reduced from 22,000 to 19,000 women as the overall enrollment goal.

You are here... 15,496 women enrolled in STAR as of March 3, 2003.

June 30, 2002 Happy 3rd Birthday STAR! As of this date, 13,647 women enrolled in STAR and 118,797 women had their breast cancer risk assessed.

11,000

June 30, 2001 Happy 2nd Birthday STAR! As of this date, 10,473 women enrolled in STAR and 89,838 women had their breast cancer risk assessed.

June 30, 2000 Happy 1st Birthday STAR! As of this date, 6,136 women enrolled in STAR and more than 47,000 women had their breast cancer risk assessed.

5,500

2,750

July 1, 1999 Enrollment to STAR Began

News Flash:

STAR Sample Size to Decrease to 19,000 Women

DL Wickerham, MD, STAR Protocol Officer & NSABP Associate Chairman

This is exciting news!

When the trial was planned it was designed to include enough women that would allow us to answer the research questions the trial was asking. That number (referred to as the *sample size*) was 22,000 and it was a conservative estimate. Plans were also made to reevaluate the sample size once the study was underway. This reevaluation took place in the Fall of 2002 and in conclusion, it was observed that the women who had entered STAR were at greater risk for developing breast cancer than originally anticipated. This factor led to the recommendation that the sample size be reduced to from 22,000 to 19,000 women.

The independent Data Monitoring Committee (DMC) for STAR reviewed the reevaluation and agreed with the sample size decrease. The information was further reviewed and approved by the STAR Steering Committee.

- Based on the current level of activity in the trial, it should still take us about another year and one-half to complete accrual. But, it doesn't have to take that long!
- As participants in STAR you too can help with the process. We invite you to tell your friends, family members, and colleagues about STAR. Potentially interested women can turn to our new Web site, **www.breastcancerprevention.com** *(See article on Page 3)*, to calculate their five year and lifetime breast cancer risk and to locate a STAR site near them. **Let your voices be heard!**
- **In the meantime, continue the fantastic job of taking your study-related drugs and meeting with your STAR physician and coordinator to obtain follow-up care.**

Frequently Asked Questions

Why did the NSABP perform a reassessment of the sample size?
A reassessment of the STAR sample size was planned before the trial began.

Why will the sample size be decreased?
The average risk of developing breast cancer (as calculated by the Gail Model) among the more than 14,000 participants enrolled thus far is substantially higher than projected, and participant's protocol compliance is in keeping with the original estimates. Therefore, it has been determined that the study can be completed on schedule with the same statistical power, but with fewer participants.

Did the STAR Data Monitoring Committee (DMC) review the reassessment?
This reassessment was presented by the NSABP at the regularly scheduled STAR Data Monitoring Committee (DMC), an independent review board that oversees all data produced by STAR, meeting on October 4, 2002. Subsequently, the committee recommended the sample size reduction.

The DMC's recommendation was then presented to the STAR Steering Committee who voted to accept the recommendation.

What next steps will the NSABP be taking?
A formal protocol amendment will be submitted to the National Cancer Institute (NCI) for approval, and also filed with the U.S. Food and Drug Administration (FDA) and the Canadian Health Products and Food Branch (HPFB). Once those actions are completed and the amendment approved, the amendment will be sent to all STAR sites for submission to their local Institutional Review Board (IRB) for approval.

Does the sample size reduction affect the study's minority recruitment goal?
No, the NSABP remains committed to enrolling a significant number of women from minority racial and ethnic groups. All populations of women should participate in STAR so that the information that is gathered is applicable to everyone.

...Continued from page 1

Co-STAR: STAR Sub-Study on Memory, Mood, and Sleep Habits Seeks Participants Age 65 and Older

- *"There is no reason not to do it, no additional drug therapy to take. I thought it was very intriguing at my age to try and measure my mental acuity."*
  – **Co-STAR participant, Oregon**
- *"It really was fun, very interesting. I liked the visual activities and drawing designs best. I didn't mind any of the tests at all."*
  – **Co-STAR participant, Minnesota**
- *"They (the tasks) made me stop and think what all is involved in the human thinking process and memory."*
  – **Co-STAR participant, Minnesota**

What's Involved?

If you agree to participate in Co-STAR, you will be asked to perform several memory tasks that take about two hours to complete. The tasks are performed once a year, usually at your local doctor's office. We asked some Co-STAR participants to comment on the tasks and here's what they said.

How Do I Join?

If you are interested in participating in Co-STAR or learning more about the study, please contact your STAR coordinator, or call the Co-STAR Coordinating Center's toll-free number at 1-866-716-9094.

BreastCancer Prevention .Com

New NSABP Web Site Enables Women to Calculate Their 5-Year and Lifetime Breast Cancer Risk

The NSABP launched a new Web site, ***www.breastcancerprevention.com*** that educates women about their own breast cancer risk and provides information about STAR.

Breast cancer will strike 200,000 women in North America in this year alone and over 40,000 women will succumb to the disease. Until recently, women had no way to accurately estimate their individual risk for developing breast cancer, nor did they have options to prevent the disease. Women are often told that one in eight women will be diagnosed with breast cancer and while this figure increases awareness, it offers little personally meaningful information.

Researchers from the NSABP and the National Cancer Institute (NCI) developed 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 has been scientifically analyzed and found to be reliable.

Prior to entering STAR you filled out a Risk Assessment Form to determine your individual risk for developing breast cancer. This Web site, ***www.breastcancerprevention.com***, uses the same calculations. However, where there are limits to filling out a form and waiting for the results, this Web site will allow the NSABP to reach thousands, if not millions of women around the world at the click of a button.

Women tend to overestimate their breast cancer risk which can lead to increased anxiety about developing the disease. The information that women will get about their personal breast cancer risk from this Web site will allow them to have personal conversations with their primary care doctor in order to map out a strategy for good breast care.

A decade ago, women at increased risk for breast cancer had no option other than vigilant screening designed to detect the disease in its earliest stage—that no longer is the case.

Women who visit this Web site can also access information about STAR.

Tell Your Friends and Family Members

"As STAR participants, we hope that you will share this Web site with your friends and family members who may be at increased risk for breast cancer," says D. Lawrence Wickerham, M.D., associate chairman for the NSABP and STAR protocol officer. "We strongly encourage that all women go through this risk assessment process to learn more about their breast cancer risk. Women who learn that they are at an increased risk for developing breast cancer can find a STAR site in their own community to discuss their results in further detail."

Bookmarks!

The NSABP has provided each STAR site with *www.breastcancerprevention.com* bookmarks. Please give some to your friends, family, churches, social organizations, and, our favorite, your local book stores and libraries!

Reflections
From Inside a Clinical Trial

Reflections... was submitted by **Mabel Goodpaster of Kansas City, Missouri**, a BPCT and STAR program coordinator and STAR participant at the ***CCOP, Kansas City Clinical Oncology Program (Baptist Medical Center)***. She has given permission for the NSABP to print this article in *Constellation*. The thoughts are her own and we thank her for sharing them with all of us. If you would like to share your experiences "from inside a clinical trial," please send them to the NSABP *(address available on back page)* and you too may see your story highlighted in an upcoming issue of Constellation.

My sister decided to stop her hormone therapy after the Women's Health Initiative (WHI) study results on Prempro gained national publicity. Based on her medical history of questionable mammograms and ultrasounds as well as fibrocystic breasts, she realized that her breast cancer risk could be high. After completing the STAR risk assessment form, her suspicions were right and her gynecologist and breast surgeon agreed with her decision to stop taking hormones.

Nothing is more important than our family, our health, and our personal faith.

My husband was one of the first Kansas City men who enrolled in the 1993 Prostate Cancer Prevention Trial (PCPT). He completed seven years of therapy taking either finasteride or placebo and also underwent a prostate biopsy at the end of the study. Now he has signed a consent form to enter the second prostate cancer prevention study being conducted by the Southwest Oncology Group (SWOG). For another eleven years he will be participating in SELECT, the Selenium and Vitamin E Cancer Prevention Trial, that will look at the effects of selenium and vitamin E on prostate cancer in healthy men age 55 or older.

As a sister, wife, mother, and grandmother, I believe that what we are doing will benefit future generations.

I have two granddaughters in college – the oldest is in graduate school at Duke University. They are very fortunate to have these learning opportunities. However, as participants in clinical trials aimed at prevention, we are giving them another kind of opportunity-- possibly a life without cancer.

Nothing is more important than our family, our health, and our personal faith.

As of July 25, 2002, I had been off of my hormone therapy, Premarin, for ninety days, randomized to STAR, and immediately started to take the two daily study pills. On that day almost 14,000 women had already enrolled in STAR, so my decision didn't seem too significant to anyone else but me. My personal commitment to join STAR only came after being "inside a clinical trial" for over nine years. I am a STAR program coordinator who also entered women to the first Breast Cancer Prevention Trial (BCPT).

At the time when BCPT opened in April 1992, I was directing the multi-disciplinary cancer second opinion panel in Kansas City and was asked to provide a letter of support for the BCPT. I cannot tell you why, but when the BCPT was explained I said that we would provide that letter. And, to my amazement, I proclaimed that I wanted to be the person working on the study. My full-time employment on BCPT began in March 1993 and was made possible by a three-year grant through our local hospital foundation, which was extended when our hospital became part of the Kansas City Clinical Oncology Program (KCCOP) in June 1995.

My commitment to the cancer prevention began in 1988 and 1989 when my healthy mother was diagnosed and began fighting her battle with advanced stage colon cancer. Her medical oncologist was and still is a 24/7 clinical researcher who exposed me to a crash course in Oncology Clinical Trials 101.

My mother was a "single parent," who raised two daughters years before "single parent" became a household word. After she died I knew that working in the business world with my title of Executive Vice President and the 23 years with the same company just to watch the financial bottom-line was no longer a part of my life priorities. Salary and annual bonuses no longer seemed to matter.

I was very fortunate to learn more about oncology by listening to pathologists, diagnostic radiologists, surgeons, medical and radiation oncologists discuss and review a cancer patient's medical records, pathology slides, x-rays, and treatment options with cancer patients and their families. I jokingly say that I unofficially received a medical degree within those four years. This multi-disciplinary panel of experts and educators not only helped the cancer patients they treated, but also prepared me for being *inside a clinical trial*.

So, why did I decide to go off Premarin? I started taking Premarin once a day after a hysterectomy in January 1982. Within that time I had tried unsuccessfully a couple times to stop the little maroon pills.

But, after an annual examination in April 2002, my physician and I agreed that I should enter STAR. My mind was made up! I knew all the information about hormone replacement therapy that I needed, now I was "mind ready" to stop. I also knew about the two STAR study drugs, tamoxifen and raloxifene, and was ready to take either.

Another big factor in my personal decision to become a STAR participant is the KCCOP's BCPT and STAR participants that I have been fortunate enough to know. Each one of these women gave a lot of thought to the risks and benefits of being enrolled in these trials. They chose to take their daily pills, go to follow-up examinations, and have not allowed menopausal symptoms to stop them from pursuing their goal. Even our BCPT women who found out at the end of the trial that they were taking a placebo never wavered and have now tirelessly entered STAR to continue their life long contribution to breast cancer prevention research.

How can I, as their coordinator, do anything less than join them?

STAR participants frequently tell me that they are not only participating in this study for themselves, but that they are doing this for their children and their children's children and for future generations. I am no different.

My granddaughters lost their paternal great grandmother (Nanaw) and their maternal grandmother to cancer. I would like them to have a paternal grandmother that is doing something to prevent this disease.

Ever since my two granddaughters were little, we have always talked about "making memories." I hope that this can be a memory that Natalie and Valerie will always value.

–For my precious granddaughters, let's make a memory that lasts forever!

...Continued from page 1

The Rise & Fall of Hormones

protect against subsequent cardiovascular events. Researchers also found that CHD events increased by 52% during the first year of HRT use. Women taking hormones were also 2.9 times more likely to suffer venous thromboembolic events than women in the placebo group.[7]

In the Estrogen Replacement Atherosclerosis (ERA) trial, women with coronary artery disease were assigned to either HRT or placebo. Although researchers found that HRT reduced low-density lipoprotein (LDL or "bad") cholesterol levels, the treatment did not alter the progression of coronary atherosclerosis as assessed by measurement of the coronary artery vessel diameter. The rate of cardiovascular events were also similar for both groups.[8]

More recently, the Women's Health Initiative (WHI) published data from its estrogen plus progestin arm that showed a 41% increase in strokes, a 29% increase in heart attacks, and doubled rates of blood clots in the legs and lungs. This means that every year per 10,000 women on estrogen plus progestin there could be eight more strokes, seven more CHD events, and eight more pulmonary emboli.[4]

Why was the Women's Health Initiative (WHI) estrogen plus progestin arm stopped early?

An independent Data and Safety Monitoring Board (DSMB) began monitoring the trial in 1997 using a global index of monitored outcomes as an overall balance of risks and benefits to assist the DSMB in determining whether or not the trial should be halted. While reviewing the data from the tenth interim analysis the DSMB found that cardiovascular adverse events were persisting; that breast cancer events had surpassed the protocol designated boundary; and the global index indicated overall harm. Given these data the DSMB concluded that the net harm of HRT (1.9 events per 1000 person-years) outweighed the possible benefits and recommended the early stopping of the estrogen plus progestin arm.[4]

What are the benefits associated with HRT?

There are some benefits derived from HRT besides the well-known relief of menopausal symptoms. Data from WHI indicate that relatively there were 37% fewer colorectal cancers and 34% fewer hip fractures (24% fewer total fractures) associated with HRT as compared to the placebo group. This equates to an absolute risk reduction of six fewer colorectal cancers and five fewer hip fractures per 10,000 person-years.[4]

How does this information relate to women in general?

Estrogen plus progestin has been shown to have a detrimental effect on the cardiovascular system. Women taking HRT for the prevention of heart disease should stop and consult their doctor about other effective alternatives, such as lifestyle changes, and cholesterol or blood pressure lowering drugs.[14]

Estrogen plus progestin does slightly reduce the incidence of osteoporosis-related fractures, but women with this concern should consult their doctor. They need to weigh the risks and benefits of this therapy with the risk of heart disease, stroke and breast cancer. Alternative approaches should be discussed before they make their choice.[14]

Estrogen plus progestin is considered effective and safe for short-term use (2 to 3 years) in the management of menopausal symptoms. Individual benefits may outweigh the associated risks. There are also alternative methods of managing these symptoms. Women should talk to a health care professional about their personal risks and needs.[14]

How does this information relate to STAR?

The two selective estrogen receptor modulators (SERMs) used in STAR have some of the beneficial effects of HRT, while eliminating some of the risks. Each SERM has its own risk/benefit profile, and careful consideration must be given before any decision is made.

Tamoxifen has been shown to reduce the overall risk of breast cancer by 49%[9], while raloxifene has shown potential for breast cancer risk reduction.[10] This is in contrast to HRT's increased risk of breast cancer. Both of these SERMs, like HRT, have been shown to reduce the incidence of osteoporotic fracture events.[9, 11] Raloxifene is approved by the U.S. Food and Drug Administration (FDA) for the prevention and treatment of osteoporosis. Although both study drugs increase the incidence of some menopausal-related symptoms rather than reducing them, these may be managed with remedies other than HRT. While risk of thrombosis does increase with both tamoxifen[9] and raloxifene[11], it also increases to the same degree with HRT.[4, 7]

Finally, the WHI provides indisputable proof of the value and need for randomized clinical trials before drugs are prescribed to treat or prevent a disease. Women in STAR are helping us obtain solid information on the benefits and risks of raloxifene before it is widely prescribed to prevent breast cancer.

For the Man in Your Life

Two Cancer Research Groups Partner to Prevent Cancer

The NSABP and the Southwest Oncology Group (SWOG), another NCI-funded research group, are partnering to make our clinical trials known to the women and men participating in our cancer prevention studies.

SELECT, the Selenium and Vitamin E Cancer Prevention Trial, is the largest-ever prostate cancer prevention trial. Selenium can be found in water and food, especially in seafood, meats, and Brazil nuts. Vitamin E is in a wide range of foods, including vegetables, vegetable oils, nuts, and egg yolks. Previous studies suggest that selenium and vitamin E may reduce the risk of developing prostate cancer, but only a large clinical trial such as SELECT can confirm those initial findings.

The study is open to men who are in generally good health, at least age 55, and who have never had prostate cancer or other cancers (except skin cancer) within the past five years. Prostate cancer strikes African American men earlier and more often than white men, therefore African American men who are age 50 and older are eligible to enroll.

Judith Jordan, a STAR participant at MD Anderson in Houston, Texas, and her husband M.A., a SELECT participant, joined these prevention trials because cancer runs in their family and they wanted to leave a legacy of health to their descendants. They joined these trials together not only to do some good, but as support for one another. "I feel much more comfortable about M.A.'s health knowing that he is getting the best care possible and that he is being proactive in safeguarding his health by participating in SELECT," says Judith.

More than 32,000 men will participate in SELECT. With more than 400 SELECT sites across the United States, Puerto Rico, and Canada, many of them also conducting STAR, there is sure to be a SELECT site in your area. To locate a SELECT site for the man in your life, please talk to your STAR coordinator. Also, information about SELECT can be obtained by calling the National Cancer Institute's (NCI) Cancer Information Service (CIS) at **1-800-4-CANCER** (1-800-422-6237) or by visiting SWOG's Web site at **http://swog.org**.

References For
The Rise & Fall of Hormones

[1] Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53,297 women with breast cancer and 100,239 women without breast cancer from 54 epidemiological studies. Lancet 1996;347:1713-27.

[2] Colditz GA, Hankinson SE, Hunter DJ, Willett WC, Manson JE, Stampfer MJ, Hennekens C, Rosner B, Speizer FE. The use of estrogens and progestins and the risk of breast cancer in postmenopausal women. N Engl J Med 1995;332(24):1589-93.

[3] Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormone replacement therapy: Collaborative reanalysis of data from 51 epidemiological studies of 52,705 women with breast cancer and 108,411 women without breast cancer. Lancet 1997;350:1047-59.

[4] Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results from the Women's Health Initiative randomized controlled trial. JAMA 2002; 288(3):321-33.

[5] Cobleigh MA. Managing menopausal problems. In: Harris JR, Lippman ME, Morrow M, Osborne CK, editors. Diseases of the breast. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2000. p.1041-50.

[6] O'Meara ES, Rossing MA, Daling JR, Elmore JG, Barlow WE, Weiss NS. Hormone replacement therapy after a diagnosis of breast cancer in relation to recurrence and mortality. J Natl Cancer Inst 2001;93(10):754-62.

[7] Hulley S, Grady D, Bush T, Furberg C, Herrington D, Riggs B, Vittinghoff E. Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. JAMA 1998;280(7):605-13.

[8] Herrington DM, Reboussin DM, Brosnihan KB, Sharp PC, Shumaker SA, Snyder TE, Furberg CD, Kowalchuk GJ, Stuckey TD, Rogers WJ, Givens DH, Walters D. Effects of estrogen replacement on the progression of coronary-artery atherosclerosis. N Engl J Med 2000;343(8):522-29.

[9] Fisher B, Costantino JP, Wickerham DL, Redmond CK, Kavanah M, Cronin WM, Vogel V, Robidoux A, Dimitrov N, Atkins J, Daly M, Wieand S, Tan-Chiu E, Ford L, Wolmark N. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. J Natl Cancer Inst 1998;90(18):1371-1388.

[10] Cummings SR, Eckert S, Krueger KA, Grady D, Powles TJ, Cauley JA, Norton L, Nickelsen T, Bjarnason NH, Morrow M, Lippman ME, Black D, Costa A, Jordan VC. The effect of raloxifene on risk of breast cancer in postmenopausal women: Results from the MORE randomized trial. JAMA 1999;281(23):2189-2197.

[11] Ettinger B, Black DM, Mitlak BH, Knickerbocker RK, Nickelsen T, Genant HK, Christiansen C, Delmas PD, Zanchetta JR, Stakkestad J, Cluer CC, Krueger K, Cohen FJ, Eckert S, Ensrud KE, Avioli LV, Lips P, Cummings SR. Reduction of vertebral fracture risk in postmenopausal women with osteoporosis treated with raloxifene: Results from a 3-year randomized clinical trial. JAMA 1999;282(7):637-645.

[12] Nelson HD, Humphrey LL, Nygren P, Teutsch SM, Allan JD. Post menopausal hormone replacement therapy. JAMA 2002;288(7):872-81.

[14] National Heart, Lung, and Blood Institute. Facts about postmenopausal hormone therapy. National Institutes of Health 2002 [cited 7 Jan. 2003];02-5200:[n. pag.]. Available from: URL: http://www.nhlbi.nih.gov/health/women/pht_facts.htm

Constellation

is published by the
National Surgical Adjuvant Breast & Bowel Project (NSABP)
for the purpose of informing and updating all STAR participants on issues related to this clinical trial.

Questions and/or comments related to this publication and STAR may be submitted to:

NSABP Operations Center
Public Relations & Communications Section
East Commons Professional Building
Four Allegheny Center – 5th Floor
Pittsburgh, PA 15212

www.breastcancerprevention.com
www.nsabp.pitt.edu