What this study is about

A study to compare two kinds of treatments for women who were at least 70 years old and had early (stage I) breast cancer that depended on the hormone called estrogen (called "ER positive" or "ER+").

The official title of this study is: CALGB 9343 (Alliance) Evaluation of lumpectomy, tamoxifen, and irradiation of the breast compared with lumpectomy plus tamoxifen in women 70 years of age or older who have carcinoma of the breast that is less than or equal to 2 cm with clinically negative axillary nodes: A phase III study

Why the study was done

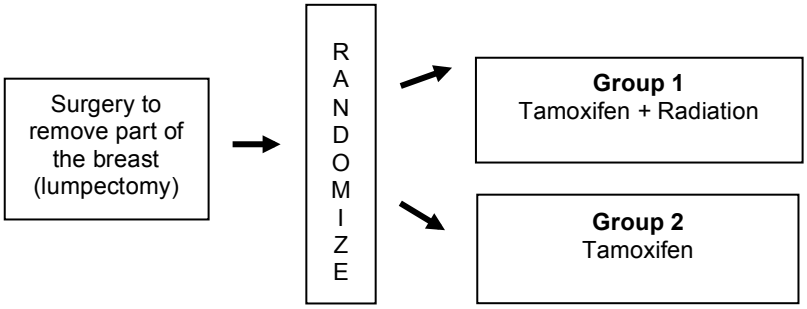
Early (stage I) breast cancer is often treated with radiation therapy (RT) after part of the breast is removed by surgery (lumpectomy). RT can lower the risk of cancer coming back in the same breast (recurrence). Radiation therapy takes weeks and patients go every weekday for treatment. Studies showed that RT had less effect in older women who take tamoxifen, so RT might not be needed. Also, some older women did not want to take RT if a drug worked as well.

This study was done to see if a common breast cancer drug called tamoxifen worked as well by itself as it did when combined with radiation therapy after a lumpectomy. Patients were women with stage I ER+ breast cancer who were at least 70 years old.

This study measured the time it took for cancer to come back in the same breast or anywhere in the body. They also tracked which patients had their whole breast removed by surgery (mastectomy) later, and compared how long they lived.

After getting a lumpectomy, all patients got tamoxifen. Half the patients got radiation therapy to the breast and half did not. Patients were put into two groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another.

Here is a picture that explains how patients were placed into one of two groups.



When did the study start and end? The study started in July 1994. All patients were enrolled by February 1999.

How many patients joined? 636 patients agreed to be in this study.

Study results

Important findings: Patients have been followed for over 10 years.

- Almost 10 of 10 patients (98%) in Group 1 were cancer-free in the breast after 10 years compared to 9 of 10 patients (91%) In Group 2.
- In Group 1, 2 of 100 patients had breast cancer return in the same breast after 10 years compared to 10 of 100 patients In Group 2.
- There was **no difference** in the number of patients who got a mastectomy later.
- There was **no difference** in the time cancer spread through the body (metastasis) or if a second cancer showed up anywhere.
- There was **no difference** in what patients died from, whether from breast cancer or other causes.

What the results mean

This means that women who get tamoxifen and radiation therapy (Group 1) have a slightly lower rate of cancer returning in the same breast. Tamoxifen alone (Group 2) works as well as tamoxifen and radiation therapy in all other ways, including how long they lived (overall survival). Older women and their doctors can now discuss whether or not they want radiation as part of their treatment. Both treatments have side effects so that should also be discussed.

These results are for women who are at least 70 years old and who have early (stage I) estrogen receptor positive (ER+) breast cancer.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Hughes KSm Schnaper LA, et al. Lumpectomy plus tamoxifen with or without irradiation in women age 70 years or older with early breast cancer: Long-term follow-up of CALGB 9343. *Journal of Clinical Oncology. 31 (19), 2013: 2382-2387*
- Hughes KS, Schnaper LA, Berry D, et al. Lumpectomy plus tamoxifen with or without irradiation in women 70 years of age or older with early breast cancer. New England Journal of Medicine. 351 (10): 971-7, 2004
- Hughes KS, Schnaper L, Berry D, et al. Comparison of lumpectomy plus tamoxifen with and without radiotherapy (RT) in women 70 years of age or older who have clinical stage I, estrogen receptor positive (ER+) breast carcinoma. [Abstract] Proceedings of the American Society of Clinical Oncology 20: A-93, 24a, 2001

This sheet reviews what is known about this research study as of *February 2014.* New Information may be available.

This study was sponsored by the Cancer and Leukemia Group B (CALGB), which is part of the Alliance for Clinical Trials in Oncology (Alliance) – a national cooperative network that runs large-scale cancer clinical trials. The Alliance s supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancer. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org/main/public/index.html.

Research studies (or clinical trials) are done to learn what works better for people in order to find, treat, or prevent cancers. Thank you for your interest in learning more about cancer research advances.