What this study is about

This study was for women who had breast cancer in their lymph nodes at the time they initially were found to have breast cancer. It was done to see if taking out less lymph nodes could correctly find cancer in women who got chemotherapy before their breast cancer surgery.

The official title of this study is: Alliance (Z1071) —A phase II study evaluating the role of sentinel lymph node surgery and axillary lymph node dissection following preoperative chemotherapy in women with node positive breast cancer (T0-4, N1-2, M0) at initial diagnosis

Why the study was done

Lymph nodes help the body protect itself from infection and disease. Lymph nodes involved with breast cancer are often under the arm, called the "axilla." The degree of lymph node involvement can be either "cN1 disease," which means the lymph nodes can move when found or "cN2 disease," which means they are stuck or matted when found.

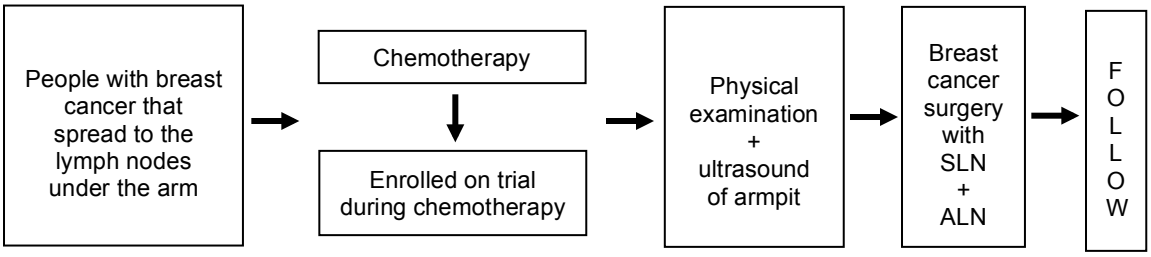
Sentinel lymph nodes (SLNs) are one of the first places a cancer spreads. For breast cancer, SLNs are found during surgery by injecting blue dye and/or tracers into the breast. Removing only SLNs (average 1-4 nodes) may cause less problems than a more common surgery that removes more lymph nodes, called " axillary lymph node dissection" (ALN surgery).

Side effects with ALN surgery can include lymphedema (arm swelling), arm numbness, and less arm movement. If SLN surgery can find out which patients do not have cancer in their lymph nodes, these patients might avoid ALN surgery and therefore have a lower risk of side effects.

This study was done to see if SLN surgery could find cancer when it was in the lymph nodes of patients who received chemotherapy. They reviewed all lymph node conditions and the number of SLNs taken at surgery.

All patients in this study had breast cancer that spread to lymph nodes under the arm when they were first diagnosed. They were treated with chemotherapy before surgery. During surgery, all patients had both SLN and ALN surgery.

Here is a picture that explains how patients were placed on this study.



When did the study start and end? The study started in July 2009. All patients were enrolled by July 2011.

How many patients joined? 756 patients agreed to be in this study, and 701 are included in these results.

Study results

Important findings: 663 women had lymph nodes that moved (cN1) and 38 women had lymph nodes that did not move (cN2).

- Sentinel lymph nodes (SLNs) are not always found. In this study, they were found in over 9 out of 10 patients (92.7%).
- When they only looked at the SLN surgery, they were able to diagnose the correct lymph node condition in 91 out of 100 patients (91.2%).

- When researchers looked at SLN surgery for cN1 disease, they did not find cancerous lymph nodes in 12 out of 100 patients (12.6%). This is called a *false negative* rate.
- SLN surgery worked better when blue dye and tracers were used to find two or more sentinel lymph nodes.

What the results mean

This study shows that SLN surgery found the correct lymph node status in patients with cancerous lymph nodes most of the time after they received chemotherapy. In most patients, SLN surgery found lymph nodes that had cancer, but it may not work as well as ALN surgery in all cases. SLN surgery should find at least two sentinel lymph nodes with blue dye and tracers. If two SLNs are not found, then ALN surgery should be done.

These results are for patients with breast cancer who have cancer in their lymph nodes, and are treated with chemotherapy before surgery.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Sentinel lymph node surgery after neoadjuvant chemotherapy in patients with node-positive breast cancer: The American College of Surgeons Oncology Group (ACOSOG) Z1071 clinical trial.
  Boughey JC, Suman VJ, Mittendorf EA, et al.
  Journal of the American Medical Association 2013 Oct 9;310(14):1455-1461

This sheet reviews what is known about this research study as of November 2013. New Information may be available.

This study was sponsored by the American College of Surgeons Oncology Group (ACOSOG). ACOSOG is part of the Alliance for Clinical Trials in Oncology (Alliance), which is a national cooperative network that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

To learn more about this trial, visit the ClinicalTrials.gov website:
http://clinicaltrials.gov/ct2/show/record/NCT00881361?term=Z1071&rank=1

Research studies (or clinical trials) are done to learn what treatments work better in people than what we already have. Thank you for your interest in learning more about cancer research advances.