

What this study is about

This study (NCCTG N9831) compared different ways to give chemotherapy (drug) treatments to people with breast cancer that is called HER2/neu positive (HER2+).

The official title of this study is:

NCCTG N9831: Phase III randomized study of doxorubicin plus cyclophosphamide followed by paclitaxel with or without trastuzumab (Herceptin®) in women with her-2-overexpressing node-positive or high-risk node-negative breast cancer

Why the study was done

There are many kinds of breast cancer. Some treatments work well in some kinds of breast cancer, while others do not work as well. About 15-20% of all breast cancers are called HER2-positive (HER2+). HER2+ breast cancer cells make too much HER2, which can be linked to faster growing cancers. This study was done to find out if adding a drug called trastuzumab (Herceptin®) to a usual (common) chemotherapy treatment helped people who have HER2+ breast cancer to live longer or live free of disease for longer time periods. Side effects were also measured for each treatment.

Patients were put into three groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one treatment was better than another.

All patients in Group A got the common mix of drugs called doxorubicin (Adriamycin®), cyclophosphamide (Cytosan®), and paclitaxel (Taxol®), which are known as AC+T. They were given four treatments of AC every 3 weeks for a 12-week period, followed by T every week for 12 more weeks.

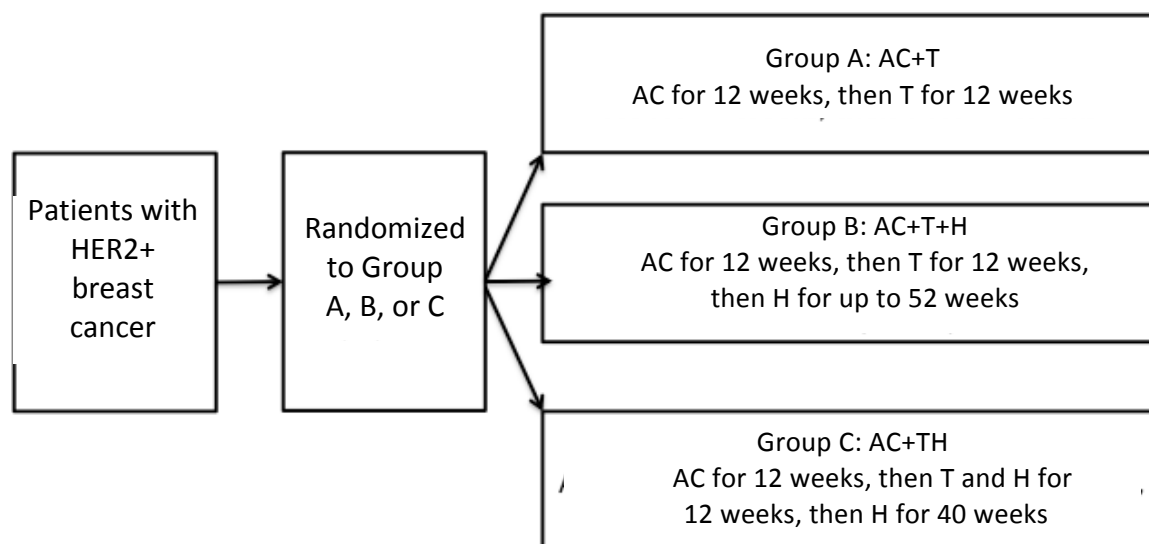
Along with the common treatment listed above (AC+T), patients in Groups B and C got trastuzumab ((Herceptin®), also known as H) in two different ways.

- In Group B, H was given once a week for 52 weeks after all of the common treatment was given.
- In Group C, H was given at the same time as T for 12 weeks and then continued once a week for 40 more weeks.

So each group looked like this:

- Patients in Group A got AC+T only.
- Patients in Group B got AC+T, then H (AC+T+H).
- Patients in Group C got AC+T and H at the same time as T (AC+TH).

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



When did the study start and end? The study started in May 2000. All patients were enrolled by April 2005.

How many patients joined? 3505 patients agreed to be in this study.

Study results

Important findings:

- 84 out of 100 people lived without cancer for 5 years in Group C
- 80 out of 100 people lived without cancer for 5 years in Group B
- 72 out of 100 people lived without cancer for 5 years in Group A

What the results mean

This study has created a new common treatment that is listed with Group C because it helps more people with HER2+ breast cancer live without cancer for 5 years. This treatment is known as AC+TH.

There were no new side effects. Side effects were treated, and most disappeared after the treatment was over. One possible long-term side effect of T is called “neuropathy” which causes tingling or pain in the hands and feet.

This study will be reviewed in the future to find out if people in one of the groups live longer, and more information about side effects will also be available.

These results are for people who are diagnosed with HER2+ 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:

- Perez EA, Suman VJ, Davidson NE, Gralow JR, Kaufman PA, Visscher DW, Chen B, Ingle JN, Dakhil SR, Zujewski J, Moreno-Aspitia A, Pisansky TM, Jenkins RB. “Sequential versus concurrent trastuzumab in adjuvant chemotherapy for breast cancer.” J Clin Oncol. 2011 Dec 1;29(34):4491-7
- Perez EA, Dueck AC, McCullough AE, Reinholz MM, Tenner KS, Davidson NE, Gralow J, Harris LN, Kutteh LA, Hillman DW, Jenkins RB, and Chen B, Predictability of adjuvant trastuzumab benefit in N9831 patients using the ASCO/CAP HER2-positivity criteria. J Natl Cancer Inst 104(2) 159-62, 2012

This sheet reviews what is known about this research study as of [November 26, 2012]. New Information may be available.

This study was sponsored by the North Central Cancer Treatment Group (NCCTG), which is part of the Alliance for Clinical Trials in Oncology – a national cooperative group that runs large cancer clinical trials. The Alliance is supported by the U.S. 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>.

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.