Alliance Public Study Result Summary

What this study is about

A breast cancer study that compared different chemotherapy (drug) treatments ways to treat older women with early breast cancer.

The full title of this study is: A randomized trial of adjuvant chemotherapy with standard regimens, cyclophosphamide, methotrexate and fluorouracil – (CMF) or doxorubicin and cyclophosphamide – (AC), versus capecitabine in women 65 years and older with node positive or node-negative breast cancer

Why the study was done

This study was done to see if a new drug was as good as common treatments for women who are at least 65 years old when they have breast cancer that has not spread.

Half the patients got a drug called capecitabine (also known as Xeloda®). Capecitabine is given in pill form and can be taken at home. The other half of the patients got a common treatment of either:

- AC: doxorubicin (Adriamycin®) and cyclophosphamide (Cytoxan®) together, or
- CMF: cyclophosphamide (Cytoxan®), methotrexate, and fluorouracil (5-FU) together

These treatments are given by vein in a doctor's office.

This study was done to see how well the treatments worked, how long it took for breast cancer to come back and which patients had fewer side effects. Patients were put into two groups by chance (randomized) to reduce differences between the groups. This was done because no one knew if one knew if one treatment was better than the other.

Study results

On average, patients in Group 1 who got the common treatments of AC or CMF had better results than patients in Group 2 who got capecitabine. Group 1 also had more side effects from treatment. Details include:

- Patients in Group 1 had twice as much time before their breast cancer came back and were less likely to die from breast cancer.
- Patients whose breast cancer depended on female hormones called estrogen or progesterone (also called hormone-positive) had more time before their cancer came back than patients whose breast cancer did not depend on female hormones (also called hormone-negative), no matter which treatment group they were in.

Results from related studies

Pill use. Three out of four patients (75%) took at least 8 out of 10 (80%) of their pills at the right time. Patients whose lymph nodes did not have cancer in them or who only had a mastectomy took fewer pills than recommended. Also, older women who had two or more chronic conditions (comorbidity) had shorter overall survival, but did not have more side effect or relapse.

Kidney function. After the study was finished, a sub-study looked at how their kidneys worked before treatment and what happened with treatment. Five factors were studied. These included side effects, the amount of medicine given (dose modification), treatment completion, how long they lived without cancer after treatment (relapse-free survival), and how long they lived (overall survival). There was no relation between how patients' kidneys worked before treatment and dose levels, who completed treatment or blood side effects for any treatment. Patients who had kidney problems, and were treated with AC, had worse side effects. As long as drug dose is watched, patients with different kidney function can be on clinical trials.

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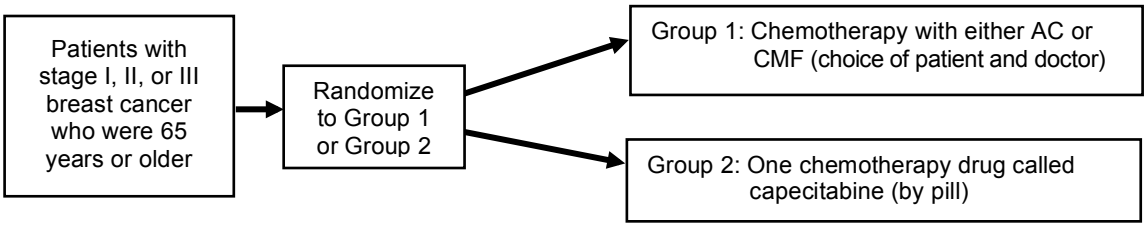
What the results mean

This means that common chemotherapy treatments (AC or CMF) work better for patients who are 65 years or older with breast cancer if they are able and willing to take chemotherapy for their disease.

These results are for patients 65 years and older, whose breast cancer has not spread to other parts of their body. This means the results are good for patients with stage I, II or III breast cancers.

How the study worked

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



When did the study start and end? The study started in September 2001. All patients were enrolled by December 2006.

How many patients joined? 633 patients agreed to be in this study. About two out of three of the patients were at least 70 years old. Breast cancer had spread to lymph nodes in seven out of 10 patients (70%).

Talk to your study doctor if you want more information about this study.

Scientific publications about this study

Details about the study can be found in these articles:

- Adjuvant chemotherapy in older women with early-stage breast cancer. Muss HB, Berry DA, Cirrincione CT, Theodoulou M, Mauer AM, Kornblith AB, Partridge AH, Dressler LG, Cohen HJ, Becker HP, Kartcheske PA, Wheeler JD, Perez EA, Wolff AC, Gralow JR, Burstein HJ, Mahmood AA, Magrinat G, Parker BA, Hart RD, Grenier D, Norton L, Hudis CA, Winer EP; CALGB Investigators. New England Journal of Medicine 360(20):2055-65, 2009
- Adherence and persistence with oral adjuvant chemotherapy in older women with early stage breast cancer in CALGB 49907: Adherence companion study 60104. Partridge AH, Archer L, Kornblith AB, Gralow J, Grenier D, Perez E, Wolff AC, Wang X, Kastrissios H, Berry D, Hudis C, Wiener E. Muss H. Journal of Clinical Oncology 28(14) 2418-2422, 2010.
- Comorbidity, chemotherapy toxicity, and outcomes among older women receiving adjuvant chemotherapy for breast cancer on a clinical trial: CALGB 49907 and CALGB 361004 (Alliance). Klepin HD, Pitcher BN, Ballman KV, Kornblith AB, Hurria A, Winer EP, Hudis C, Cohen HJ, Muss HB, Kimmick GG J Oncol Pract. 2014 Sep;10(5):e285-92. Epub 2014 Jul 29

To learn about this trial, visit the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/show/results/NCT00024102?term=CALGB+49907&rank=1

This study was sponsored by the Alliance for Clinical Trials in Oncology – 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.

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This summary lists what is known about this research study as of March 2015. New Information may be available.

We thank the people who joined this study and made it possible. *We do research to try to learn the best ways to help patients. The people who joined this study helped us to do that.*

Thank you for your interest in learning more about cancer research advances.