

Title

CALGB 49907—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

Short title: CALGB 49907: A breast cancer study that compared different chemotherapy (drug) treatments ways to treat older women with early breast cancer

Why the study was done

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

Half of the patients got a new drug called capecitabine (also known as Xeloda®). Capecitabine is given in pill form and can be taken at home.

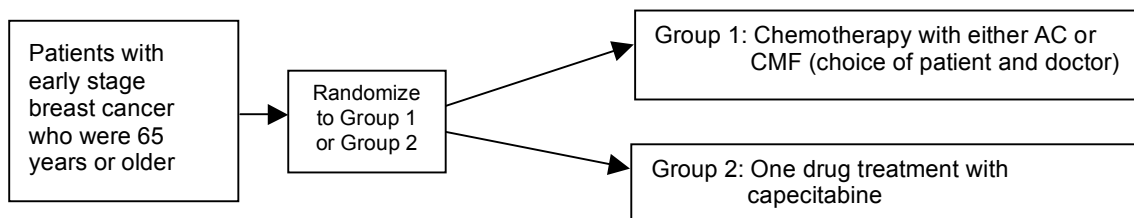
The other half of the patients got one of the usual treatments of either:

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

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

The goals of the study were 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 treatment was better than the other.

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



Researchers kept track of any side effects, and if and when a patient's cancer returned.

Some patients also agreed to a study that kept track of how often the capecitabine pills were taken.

Study results

Important findings: On average, patients in Group 1 who got the usual treatments of AC or CMF had better results than patients in Group 2 who got capecitabine, but they also had more side effects from their treatment. In addition, 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.

Other findings: In addition, three out of four patients took at least 80 percent 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.

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

How many patients participated? 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.

What the results mean

This means that **normal 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.

You can also talk with your doctor for more information.

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, Cirincione 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.

This sheet reviews what is known about this research study as of August 12, 2010. New information may be available.

This study was sponsored by the Cancer and Leukemia Group B (CALGB) – a national cooperative group that conducts large-scale cancer clinical trials. The CALGB is supported by the National Cancer Institute (NCI) and brings together scientists to develop better treatments for cancer.

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.