Alliance Public Study Result Summary
CALGB 40503

What this study is about

This study compared two different drug treatments in women beyond child-bearing age, with breast cancer that was hormone receptor-positive and had spread locally or to other areas of the body where surgery was no longer a treatment choice (advanced breast cancer).

The full title of this study is: Endocrine therapy with or without anti-VEGF therapy: A randomized, phase III trial of endocrine therapy alone or endocrine therapy plus bevacizumab (NSC 704865: IND 7921) for women with hormone receptor-positive advanced breast cancer

Why the study was done

This study was done to see if adding a newer type of drug called bevacizumab (an anti-***v***ascular ***e***ndothelial ***g***rowth ***f***actor, or anti-VEGF) to the currently accepted endocrine treatment (letrozole) would be a better treatment option than letrozole only for patients with advanced breast cancer.

The study compared the amount of time it took for tumors to show signs of growth between the two treatment groups. The study also compared how long patients lived and determined how safe it was to give patients letrozole (common brand name femara) and bevacizumab (common brand name avastin) together.

Study results

All patients treated on this study were beyond child-bearing age, had breast cancer that was hormone receptor-positive and had spread locally or to other areas of the body. At the start of treatment, patients were able to perform daily activities such as caring for themselves and chores without difficulty. Patients could have received prior drug treatment for their advanced breast cancer before agreeing to be treated on this study.

The results of the study are:

- Patients given letrozole and bevacizumab experienced a longer time before their tumor showed signs of growth or spread to other areas of the body as compared to the patients given only letrozole (4.6 months longer).
- Even though tumors responded better to treatment with letrozole and bevacizumab, there was no difference in how long the patients lived between the two groups.
- Patients treated with letrozole and bevacizumab had more serious side effects from the treatment than the patients treated with letrozole only.

Twenty-one patients (14%) of those treated with letrozole and bevacizumab had to stop treatment early due to side effects as compared to 2 patients (1%) treated with letrozole only.

The most common serious side effects experienced by patients treated with letrozole and bevacizumab were:

- 42 patients (24%) developed high blood pressure
- 19 patients (11%) developed protein in their urine
- 17 patients (10%) experienced joint aches and pains

What the results mean

The results of this study mean patients treated with letrozole and bevacizumab experienced a longer period of time before their breast tumors showed signs of continued growth or spread to other areas of the body. However, despite this positive benefit, there were more serious side effects caused by the treatment and there was no difference between the two groups in how long the patients lived.

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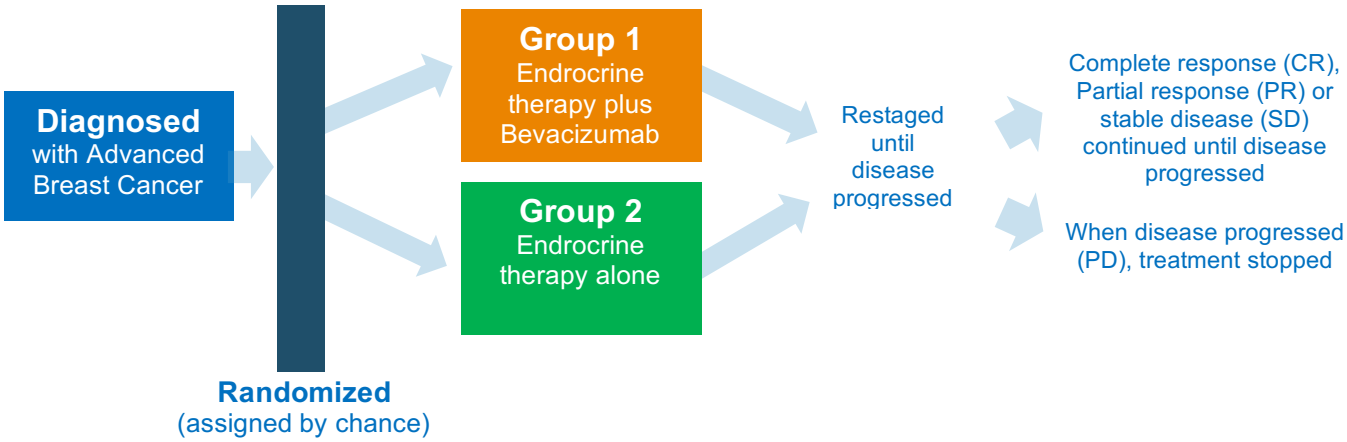
This study concluded that adding bevacizumab to the accepted endocrine treatment of letrozole for the treatment of hormone receptor-positive, advanced breast cancer is of no benefit. The addition of bevacizumab caused too many serious side effects and patients did not live any longer.

How the study worked

Patients were assigned by chance (randomized) to one of two groups. This made sure that each patient had the same chance of being in any study group. Half of the patients got letrozole and the other half got letrozole and bevacizumab. Patients remained on treatment until their breast cancer showed signs of growth or continued to spread to other parts of the body.

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



When did the study start and end? The study started in May 2008. All patients were enrolled by November 2011.

How many patients joined? 350 patients agreed to be in this study. All patients were women with hormone receptor- positive advanced breast cancer.

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

Scientific publications about this study

This summary includes information in the following article:

- **Phase III Trial Evaluating Letrozole as First-Line Endocrine Therapy With or Without Bevacizumab for the Treatment of Postmenopausal Women With Hormone Receptor-Positive Advanced-Stage Breast Cancer: CALGB 40503 (Alliance).** Dickler MN, Barry WT, Cirrincione CT, Ellis MJ, Moynahan ME, Innocenti F, Hurria A, Rugo HS, Lake DE, Hahn O, Schneider BP, Tripathy D, Carey LA, Winer EP, Hudis CA. J Clin Oncol. 2016 Aug 1;34(22):2602-9. doi: 10.1200/JCO.2015.66.1595. Epub 2016 May 2.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/results/NCT00601900

This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group that runs large cancer clinical trials. The Alliance is supported by the National Cancer

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Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of May 2016.
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.