Alliance Public Study Result Summary
CALGB 40502

What this study is about

This study compared different drug treatments (chemotherapy) for adults with breast cancer that has returned or spread throughout the body (metastatic breast cancer).

The full title of this study is: A randomized phase III trial of weekly paclitaxel compared to weekly nanoparticle albumin bound nab-paclitaxel or ixabepilone with bevacizumab as first-line therapy for locally recurrent or metastatic breast cancer

Why the study was done

This study was done to see if either ixabepilone (common brand name ixempra) or nab-paclitaxel (common brand name abraxane) could delay the time it took for breast cancer to grow when compared to a usual (standard) chemotherapy treatment with a drug called paclitaxel (common brand name taxol). All people on the study also got a drug called bevacizumab (common brand name avastin).

Researchers looked at how long it took for cancer to grow or spread to new places, and at the side effects people had in each of the treatment groups.

Study results

These results are for people with breast cancer that has returned or spread to parts of the body beyond the breast and underarm lymph nodes. This is called metastatic breast cancer. People in this study had not yet had any chemotherapy for metastatic breast cancer.

The study found that neither ixabepilone nor paclitaxel delayed the time it took for cancer to grow or spread when compared to paclitaxel.

The average time it took for cancer to grow or spread was:

- 7.4 months for ixabepilone (Group 1)
- 9.3 months for nab-paclitaxel (Group 2)
- 11 months for paclitaxel (Group 3)

Serious side effects were more common with both ixabepilone and nab-paclitaxel than with paclitaxel. Side effects included:

- Numbness and tingling in hands and feet that limited daily activities. This happened in:
  - More than 2 in 10 patients (25%) who got ixabepilone (Group 1)
  - Almost 3 in 10 patients (27%) who got nab-paclitaxel (Group 2)
  - Almost 2 in 10 patients (18%) who got paclitaxel (Group 3)
- Severe tiredness (fatigue). This happened in:
  - More than 1 in 10 patients (15%) who got ixabepilone (Group 1)
  - More than 1 in 10 patients (16%) who got nab-paclitaxel (Group 2)
  - 1 in 10 patients (10%) who got paclitaxel (Group 3)
- Severe nausea happened in:
  - Less than 1 in 10 patients (6%) who got ixabepilone (Group 1)
  - Less than 1 in 10 patients (5%) who got nab-paclitaxel (Group 2)
  - 0 patients who got paclitaxel (Group 3)
- Very low white blood cells that fight infection. This happened in:
  - Less than 1 in 10 patients (7%) who got ixabepilone (Group 1)
  - About 5 in 10 patients (51%) who got nab-paclitaxel (Group 2)
  - Almost 2 in 10 patients (18%) who got paclitaxel (Group 3)

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What the results mean

In patients with no previous chemotherapy treatment for breast cancer that had spread, paclitaxel delayed the growth or spread of cancer in more patients than ixabepilone. Nab-paclitaxel was not better at delaying growth or spread than paclitaxel. There were fewer serious side effects with paclitaxel than either of the other drugs.

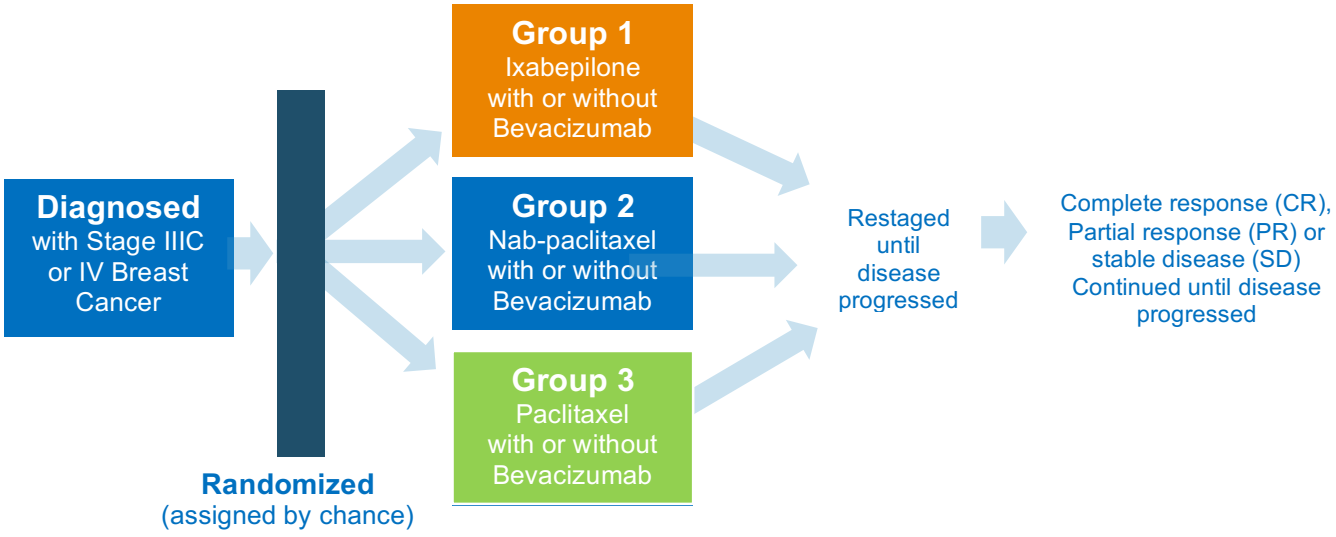
This means that paclitaxel is still the recommended treatment for patients with breast cancer that has spread.

How the study worked

All three chemotherapy drugs were given weekly for three weeks followed by a one-week break. All patients also received bevacizumab, a drug that targets blood vessels.

All patients were assigned by chance (randomized) to one of three groups. This made sure that each patient had the same chance of being in any study group.

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



When did the study start and end? The study started in October 2008. All patients were enrolled by December 2011. This study was done in the U.S. and Canada.

How many patients joined? 799 patients were enrolled on this study. 783 patients received treatment.

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

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Scientific publications about this study

This summary includes information from the following article:

- **Randomized Phase III Trial of Paclitaxel Once Per Week Compared with Nanoparticle Albumin-Bound Nab-Paclitaxel Once Per Week or Ixabepilone with Bevacizumab as First-Line Chemotherapy for Locally Recurrent or Metastatic Breast Cancer: CALGB 40502/NCCTG N063H (Alliance).** Rugo HS, Barry WT, Moreno-Aspitia A, Lyss AP, Cirrincione C, Leung E, Mayer EL, Naughton M, Toppmeyer D, Carey LA, Perez EA, Hudis C, Winer EP. J Clin Oncol. 2015 Jul 20;33(21):2361-9. doi: 10.1200/JCO.2014.59.5298. Epub 2015 Jun 8.

Other details about the study can be found in this article:

- **Kinetic-Pharmacodynamic Model of Chemotherapy-Induced Peripheral Neuropathy in Patients with Metastatic Breast Cancer Treated with Paclitaxel, Nab-Paclitaxel, or Ixabepilone: CALGB 40502 (Alliance).** Mehrotra S, Sharma MR, Gray E, Wu K, Barry WT, Hudis C, Winer EP, Lyss AP, Toppmeyer DL, Moreno-Aspitia A, Lad TE, Valasco M, Overmoyer B, Rugo H, Ratain MJ, Gobburu JV. AAPS J. 2017 Jun 15. doi: 10.1208/s12248-017-0101-9.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00785291

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 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 July 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.