

CALGB 9840: a breast cancer study that compared ways to give treatment

Title

A phase III study to compare weekly Taxol (paclitaxel) treatment to normal 3 week Taxol treatment, with or without Herceptin (trastuzumab) for patients with breast cancer that has spread to other parts of their body (metastatic).

Sponsor

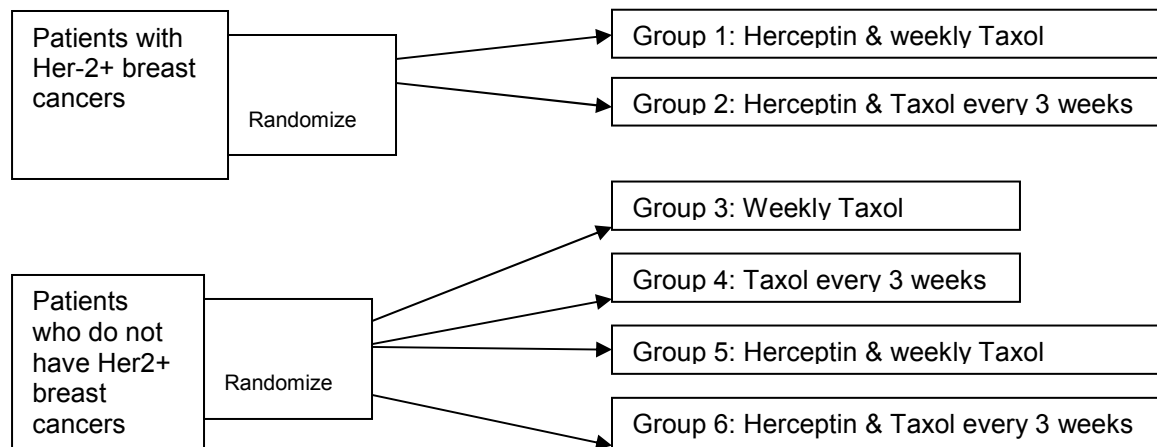
Cancer and Leukemia Group B (CALGB), a government-sponsored clinical trial program. CALGB is one of the “cooperative groups” that is funded in part by the U.S. National Cancer Institute (NCI).

Why the study was done

This study compared different times to give a drug, called paclitaxel or Taxol® to breast cancer patients. Half of the patients got a small amount of Taxol every week, and half of the patients got a larger amount of Taxol every 3 weeks. The purpose was to see which patients lived longer.

This study also included one more drug, called trastuzumab or Herceptin®, which was given with Taxol. Herceptin is known to stop cancers that have too much of a protein called Her-2/neu, which helps them grow faster. This kind of breast cancer is normally called “HER2 positive” (HER2+). If a cancer does not have too much Her-2/neu, it is called “HER2 negative” (HER2-). Herceptin was given to all patients who had HER2+ cancers. Only half of the patients with HER2- tumors were given Herceptin.

Here is a picture of how patients were put into 6 groups, by chance (randomized), so no one could think one treatment was better than the others.



Study results:

There were 585 patients in this study. The study started in July 1998 and ended in November 2003.

These are the important differences found in the study.

The patients who took a smaller dose of Taxol every week compared to a higher dose of Taxol every three weeks:

- 1) Had their tumors shrink (42% vs. 29%).
- 2) Took longer to have their cancer grow (9 months vs. 5 months).
- 3) Lived longer (average time: 24 months after treatment vs. 12 months after treatment).
- 4) Had more numbness in their hands and feet (neuropathy) (1 in 4 patients vs. 1 in 8 patients).

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What the results mean

This means that **weekly Taxol** shrank more tumors, and delayed tumor growth (disease progression) longer than Taxol given every 3 weeks, whether patients got Herceptin or not. The study also found there was **no gain** from Herceptin for patients who do not have HER2+ breast cancer.

These results are for patients over 18 years old, whose breast cancer has spread to other parts of their body, known as Stage IV or metastatic breast cancer. Patients who had past treatment that did not include Taxol can be helped by weekly Taxol. Herceptin is ok for patients with Her2+ tumors if they have not had it before.

Scientific Publications Resulting From This Study

Details are offered in these articles:

- *Serum HER2 extracellular domain (ECD) levels and efficacy of weekly (W) or every 3-weekly (q3W) paclitaxel (P) with or without trastuzumab (T) in patients (pts) with metastatic breast cancer (MBC): CALGB 150002/9840. Seidman AD, Broadwater G, Carney WP, Dressler LG, Berry DA, Norton L, Hudis CA, Winer EP, Ellis MJ, Harris LN Proc ASCO:558, 2005 - Published Date 5/16/2005*
- *Seidman AD, Berry DA, Cirrincione CT, Harris LN, Dressler LG, Muss HB, Naughton M, Norton L, Winer EP, Hudis CA. Proc ASCO:512, 2004.*

You can also talk with your doctor for more information.

Reviewed by

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Released on: May 2, 2009