

CALGB 9840: A breast cancer study that compared timing and different ways to give treatment to patients whose cancer had spread to other parts of their body (metastatic breast cancer)

## Title

**CALGB 9840 – A phase III study of paclitaxel via weekly 1 hour infusion versus standard 3 hour infusion every 3 weeks with Herceptin (trastuzumab) (NSC #688097) in the treatment of patients with/without HER-2/neu-overexpressing metastatic breast cancer**

## Sponsor

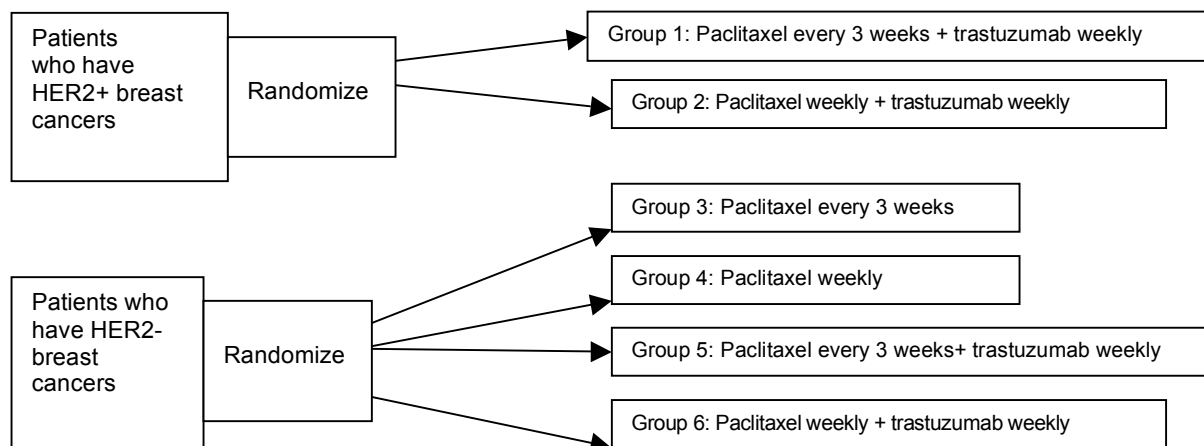
The Cancer and Leukemia Group B (CALGB) is a national cooperative group that conducts large-scale cancer clinical trials. It is supported by the National Cancer Institute (NCI) and brings together scientists to develop better treatments for cancer.

## Why the study was done

This study compared different schedules to give a drug called paclitaxel (Taxol®) to breast cancer patients who have metastatic disease (cancer that has spread to other parts of their body). Paclitaxel is known to attack cancer cells as they divide to create new cells. Half of the patients were given a smaller amount of paclitaxel every week, and the other half were given a larger amount of the drug every three weeks. The goal was to see which way of giving this drug would keep patients' cancer from getting worse for the longest amount of time.

The study was changed part way through to look at another drug called trastuzumab (Herceptin®) that was given with paclitaxel. Trastuzumab is known to slow the growth of cancers that have an excess of a protein called HER-2/neu, protein which helps them grow faster. This kind of breast cancer is normally called *HER2 positive (or HER2+)*. If a cancer has the normal amount of HER-2/neu, it is called *HER2 negative (or HER2-)*. Under the changed study, trastuzumab was given to all patients who had HER2+ cancers. Another goal of the changed study was to find out if patients with HER2- cancers did better with trastuzumab. Patients with HER2- cancers were randomized (selected by chance) to receive trastuzumab or not.

Here is a picture of how patients were put into six groups in the second part of the study, by chance (randomized), since no one knew in advance if one treatment would be better than the other.



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## Study results

**When did the study start and end?** It started in July 1998 and ended in November 2003.

**How many patients participated?** 585 patients were entered on the original study, and 158 more patients from a prior CALGB study who received the same treatment were included in the study results.

**Important findings:** Patients who took a weekly dose of paclitaxel compared to those who took the same drug every three weeks:

- Had their tumors shrink more often (42 percent of patients instead of 29 percent).
- Took longer for their cancers to grow back (9 months instead of 5 months).
- Had numbness in their hands and feet (a condition called neuropathy) more often (1 in 4 patients instead of 1 in 8 patients).
- Lived longer (average time was 24 months after treatment versus 12 months after treatment).  
However this result is not as strong as the results for tumors shrinking or cancers growing back.

The study also found there was **no** benefit from trastuzumab for patients who have HER2- breast cancer.

## What the results mean

The study results mean that **weekly paclitaxel** shrank more tumors, and delayed tumor growth (disease progression) longer than paclitaxel given every three weeks, if patients were given trastuzumab or not.

These results are for patients over 18 years old, and whose breast cancer has spread to other parts of their body (stage IV or metastatic breast cancer). Patients who had past treatment that did not include paclitaxel can be helped by weekly paclitaxel. Trastuzumab is commonly used for patients with HER2+ tumors if they have not had it before, because it has helped when it was added to paclitaxel in other studies.

## Scientific publications about this study

Details about the study can be found in this article:

- Randomized phase III trial of weekly compared with every-3-weeks paclitaxel for metastatic breast cancer, with trastuzumab for all HER-2 overexpressors and random assignment to trastuzumab or not in HER-2 nonoverexpressors: Final results of Cancer and Leukemia Group B protocol 9840  
Seidman AD, Berry D, Cirrincione C, Harris L, Muss H, Marcom PK, Gipson G, Burstein H, Lake D, Shapiro CL, Ungaro P, Norton L, Winer E, Hudis C  
*Journal of Clinical Oncology, Vol 26, No 10 (April 1), 2008: pp. 1642-1649*

**You can also talk with your doctor for more information.**

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