

Title

CALGB 80303—A randomized phase III trial of gemcitabine plus bevacizumab (NSC#704865, IND#7921) versus gemcitabine plus placebo in patients with advanced pancreatic cancer

Short title: CALGB 80303: A pancreatic cancer study that compared two treatments for people whose cancer could not be removed by surgery

Why this study was done

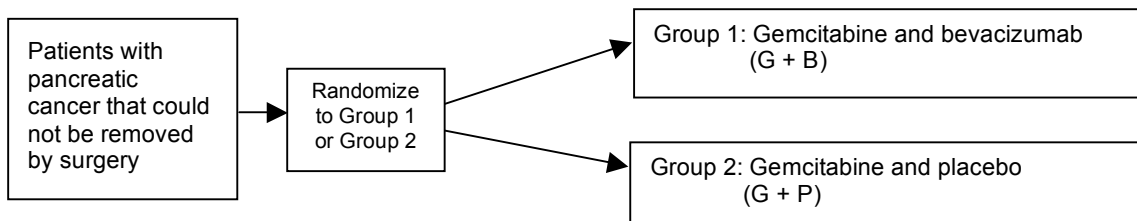
This study compared two treatments for people with pancreatic cancer that could not be removed by surgery. Half the patients were given a combination of two drugs, gemcitabine (Gemzar[®]) and bevacizumab (Avastin[®]). The other half were given gemcitabine and placebo (a non-active agent).

Gemcitabine is a chemotherapy drug known to attack cancer cells as they divide to create new cells. It is commonly used to treat pancreatic cancer. Bevacizumab is a newer drug that stops cancer cells from growing by cutting off their blood supply.

The goal of this study was to see which treatment would help patients with this kind of pancreatic cancer live longer.

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 another.

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



Two smaller studies (companions) were also offered to these patients, and some patients took part in them. One study looked to see if patients lived longer if they were able to care for themselves when they started treatment. The other study looked for clues in patients' DNA (a genetic map that tell cells what to do) to see who might live longer.

Study results

Important findings: Patients in both groups lived about the same amount of time, no matter which treatment they got. The study found there was **no** benefit from bevacizumab for patients with advanced pancreatic cancer. Patients in Group 1 who took G + B had more side effects such as high blood pressure. Here are some other details:

- About half of the patients who took G + B lived less than 5.8 months, and about half lived more than 5.8 months.
- Patients who were sicker when they started treatment died earlier; the average time was 2.4 months instead of almost 8 months for those who were less sick when they started treatment.

Other findings:

- Only certain patients had a change in a gene called IL-17F, and they died earlier than patients with a regular IL-17F gene. The kind of treatment did not make a difference.

- The level of pain, worries and mood got better with treatments for patients in this study.
- How well patients took care of themselves got worse even if their cancer shrank.

Early clues also showed that patients who have regular IL-17F genes may live longer than those who do not. This is the first time this information has been shown, so more studies are needed before IL-17F can be used in treatment choices.

When did the study start and end?

The study started in June 2004. All patients were enrolled by April 2006.

How many patients participated?

535 patients were treated on the study. 279 got gemcitabine and bevacizumab (G + B), and 256 were treated with gemcitabine only (G).

What the results mean

This means that the combined treatment of gemcitabine and bevacizumab (G + B) is **not better** than gemcitabine (G) for patients with pancreatic cancer that cannot be removed by surgery.

How long these pancreatic cancer patients live depends on how well they feel when they start treatment.

You can also talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in this article:

- Gemcitabine plus bevacizumab compared with gemcitabine plus placebo in patients with advanced pancreatic cancer: Phase III trial of Cancer and Leukemia Group B (CALGB 80303)
Kindler HL, Niedzwiecki D, Hollis D, Sutherland S, Schrag D, Hurwitz H, Innocenti F, Mulcahy MF, O'Reilly E, Wozniak TF, Picus J, Bhargava P, Mayer RJ, Schilsky RL, Goldberg RM
Journal of Clinical Oncology volume 28, number 22, page 3617-3622 August 1, 2010.

This sheet reviews what is known about this research study as of November 8, 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.