Title

CALGB 30402—A phase II trial of docetaxel plus cetuximab or docetaxel plus bortezomib (NSC #681239, IND #58443) in advanced non–small-cell lung cancer patients with performance status (PS) 2

Short title: CALGB 30402: A lung cancer study that compared two new drugs given to patients whose cancer spread beyond the lungs

Why the study was done

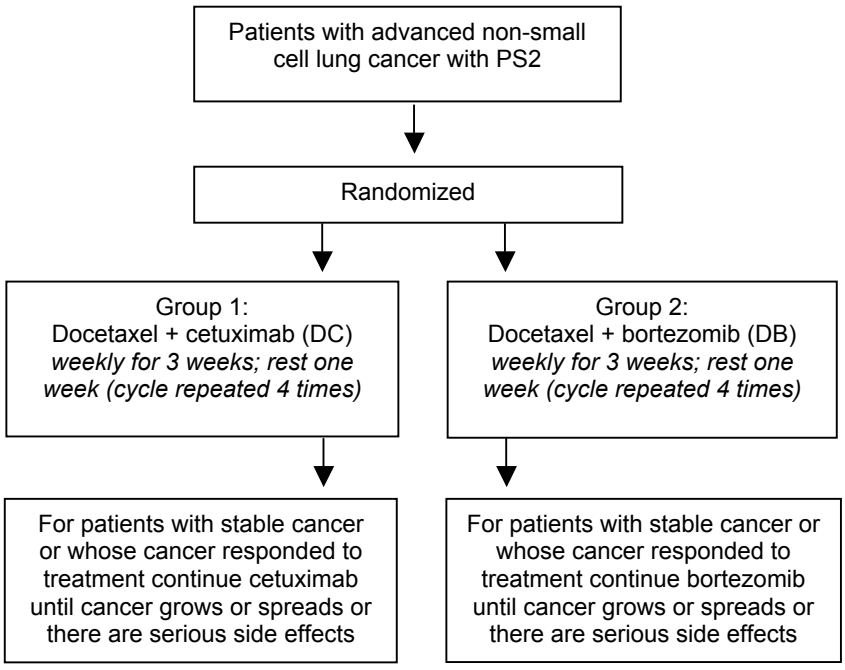
The study was done to find out if new targeted drugs help control non-small cell lung cancer, and to find out how often the cancer stayed away six months after treatment.

This study treated patients with lung cancer who were able to care for themselves and be out of bed for more than half a day, but could no longer work. This is called "performance status 2" or PS2. In this study, patients may have had chemotherapy or radiation therapy if it was more than 12 months earlier.

In the past, lung cancer patients with PS2 were treated only with chemotherapy, and had serious side effects. New targeted therapies have been made to find and kill only cancer cells, which may lower side effects. This study wanted to see if adding new targeted therapy with regular chemotherapy could help patients with PS2.

All patients got a chemotherapy drug called docetaxel (Taxotere®). Patients were then put into one of two groups to get one of the targeted therapies: either cetuximab (Erbitux®) or bortezomib (Velcade®). Patients were put into two groups by chance (randomized) to make them even and fair. This was done because no one knew if one treatment was better than the other.

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



Study results

Important findings: Only one out of three patients (33 percent) was able to take all four cycles of treatment. Most patients were able to take two cycles of treatment. The most common reason for stopping treatment was because the cancer got worse. Both groups of patients lived for about four months. Six months after the study started, half the patients were alive. In both groups the cancer did not start growing again until about 2.5 months after starting the study. In about 21 percent of the patients the cancer did not start growing again until six months after starting the study. Patients treated in Group 1 with DC (docetaxel + cetuximab) had more skin rashes and mouth sores than patients treated in Group 2 with DB (docetaxel + bortezomib), but they did not have serious blood side effects.

When did the study start and end? The study started in July 2005. The study closed in September 2006.

How many patients participated? Sixty-four patients agreed to be in this study. Fifty-nine patients were eligible and were treated on this study. The cancer had spread outside the lungs (metastatic cancer or stage 4) in eight of 10 patients (80 percent). Half of the patients were at least 70 years old.

What the results mean

In most patients, adding cetuximab or bortezomib to standard chemotherapy (docetaxel) did not stop the cancer from growing longer than six months in these lung cancer patients. Most patients with PS2 got worse before two cycles of treatment were done. In this study, adding the targeted therapy agents (cetuximab or bortezomib) did not help patients with PS2.

These results are for patients who are at least 18 years old with non-small cell lung cancer that has spread outside of the lung (metastatic cancer) who can care for themselves (PS2).

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:

- Randomized phase II trial of docetaxel plus cetuximab or docetaxel plus bortezomib in patients with advanced non–small-cell lung cancer and a performance status of 2: CALGB 30402
  Lilenbaum R, Wang X, Gu L, Kirshner J, Lerro K, Vokes E
  Journal of Clinical Oncology 27(27):4487-4491, 2009

This sheet reviews what is known about this research study as of December 1, 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.