Alliance Public Study Result Summary
CALGB 30801

What this study is about

This study compared two treatments for patients with advanced non-small cell lung cancer.

The full title of this study is: A randomized phase III double blind trial evaluating selective COX-2 inhibition in COX-2 expressing advanced non-small cell lung cancer.

Why the study was done

This study was done to see if adding a drug called celecoxib (common brand name celebrex) to the usual treatment for patients with advanced non-small lung cancer made tumors respond faster and helped patients live longer. All patients in this study had their cancer tumors tested for a marker called COX-2. Past studies have shown that cancer tumors with a lot of COX2 don't respond well to treatment.

The study was done to see if blocking COX2 with celecoxib would help tumors respond faster to the usual treatment and help patients live longer.

Study results

All patients in this study had advanced non-small cell lung cancer (NSCLC) that had spread to local or distant parts of the body, which is called stage III or IV NSCLC. All tumors were tested before patients entered the study for COX2, a common biomarker that measures stress in cells (like inflammation). Patients with tumors that had a lot of COX2 were enrolled on this study. All patients had to be able to perform daily activities such as caring for themselves and chores without problems.

When researchers looked at the results in 312 patients, there was no difference in tumor response to treatment between in two groups. The study was stopped early after this finding.

These were the most common serious side effects:

- In Group 1 (plus celecoxib)
  - Almost 3 in 10 patients (28%) had low red blood cell counts that can cause anemia and weakness.
  - Almost 2 in 10 patients (17%) had a weaker immune system that could cause infection.
  - About 1 in 10 patients (14%) had thin blood that did not clot well.
- In Group 2
  - Over 2 in 10 patients (23%) had low red blood cell counts that caused anemia and weakness.
  - Over 1 in 10 patients (15%) had a weaker immune system that could cause infection.
  - About 1 in 10 patients (11%) had thin blood that did not clot well.

What the results mean

The results of this study mean that there is no benefit in adding celecoxib to the usual treatment for advanced non-small cell lung cancer. Lung cancer does not respond better to treatment when celecoxib is added.

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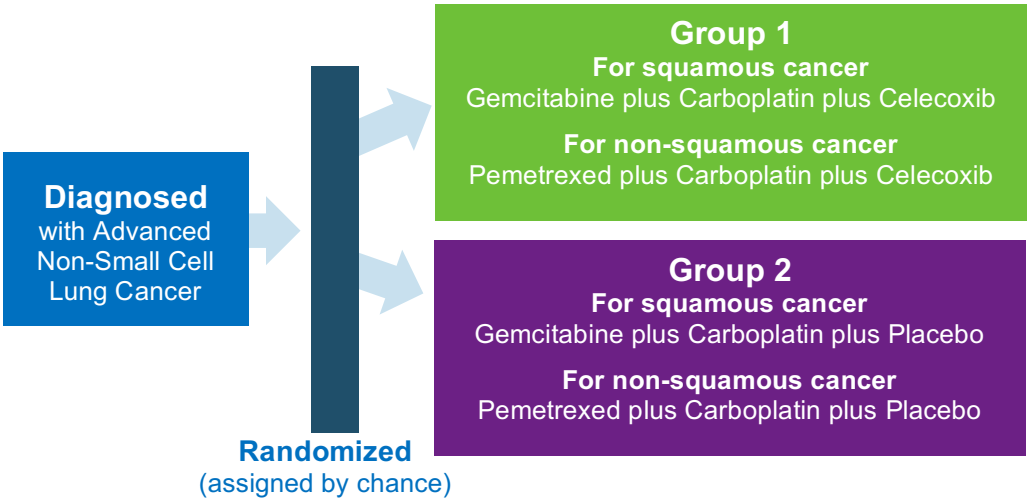
How the study worked

Patients were assigned by chance (randomized) to one of two groups. This made sure that each patient had the same chance of being in any study group. All patients stayed on treatment until their lung cancer showed signs of growth, or until side effects caused too many problems.

- Group 1 got the usual treatment for advanced non-small cell lung cancer plus celecoxib
- Group 2 got the usual treatment with a pill that had no medicine - *this is called a placebo pill*

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



When did the study start and end? The study started February 15, 2010 and was stopped on November 15, 2013.

How many patients joined? The study was stopped after 312 of the 322 planned patients were treated.

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

Scientific publications about this study

This summary includes information in the following article:

- **Phase III Randomized, Placebo-Controlled, Double-Blind Trial of Celecoxib in Addition to Standard Chemotherapy for Advanced Non-Small-Cell Lung Cancer with Cyclooxygenase-2 Overexpression: CALGB 30801 (Alliance).** Edelman MJ, Wang X, Hodgson L, Cheney RT, Baggstrom MQ, Thomas SP, Gajra A, Bertino E, Reckamp KL, Molina J, Schiller JH, Mitchell-Richards K, Friedman PN, Ritter J, Milne G, Hahn OM, Stinchcombe TE, Vokes EE. J Clin Oncol. 2017 Jul 1;35(19):2184-2192. doi: 10.1200/JCO.2016.71.3743. Epub 2017 May 10.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT01041781

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.

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This summary lists what is known about this research study as of July 2017.
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.