Alliance Public Study Result Summary
CALGB 30607

What this study is about

A study that determined how well a drug worked after treatment of chemotherapy in patients with stage IIIB-IV non-small cell lung cancer.

The full title of this study is: Randomized phase III double-blind placebo-controlled trial of sunitinib (NSC#736511, IND #74019) as maintenance therapy in non-progressing patients following an initial four cycles of platinum-based combination chemotherapy in advanced stage IIIB/IV non-small cell lung cancer

Why the study was done

This study was done to see using sunitinib (common brand name sutent) after standard chemotherapy for locally advanced lung cancer is helpful.

Study results

These results are for people with locally advanced lung cancer (stage IIIB/IV)

The study found that people who received sunitinib after chemotherapy had slower tumor growth than those who were followed without sunitinib. It also found that both those people who received sunitinib and those who did not, lived about the same amount of time. The people who received sunitinib felt less well than those who did not receive sunitinib. Specifically, they noted more problems with appetite, diarrhea, nausea/vomiting, shortness of breath and sore mouth.

The most common serious side effects included changes in blood counts, poor appetite diarrhea, rash, high blood pressure and fatigue.

What the results mean

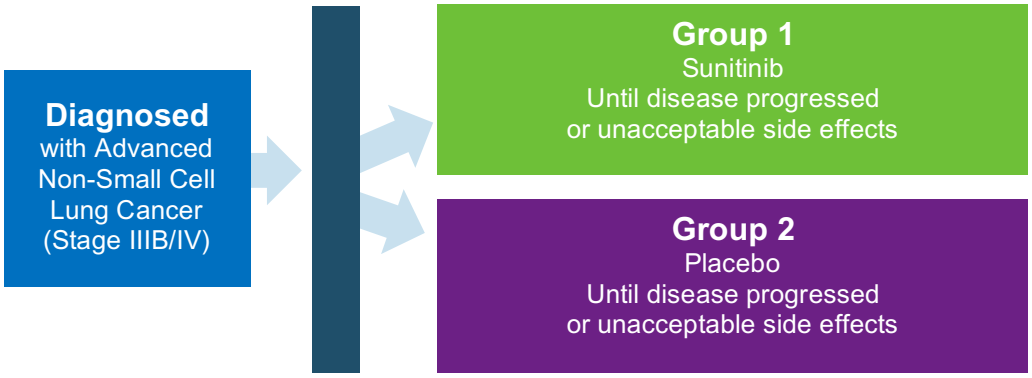
This means that people who received sunitinib after initial chemotherapy had an initial slowing of their cancer growth, but that sunitinib did not result in people living longer. Also, people who received sunitinib had more side effects and generally, felt less well. Sunitinib is not being used in this setting.

How the study worked

Patients with stage IIIB-IV non-small cell lung cancer 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.

- Group 1 got sunitinib until their cancer grew or they had unacceptable side effects.
- Group 2 got a placebo until their cancer grew or they had unacceptable side effects. A placebo is an inactive substance that was taken the same way as the drug in the Group 1, so no one knew who was taking sunitinib or the placebo.

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



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When did the study start and end? The study started in June 2008. All patients were enrolled by November 2013.

How many patients joined? 210 patients agreed to be in this study.

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:

- **Maintenance Sunitinib Following Initial Platinum-Based Combination Chemotherapy in Advanced-Stage IIIB/IV Non-Small Cell Lung Cancer: A Randomized, Double-Blind, Placebo-Controlled Phase III Study-CALGB 30607 (Alliance).** Baggstrom MQ, Socinski MA, Wang XF, Gu L, Stinchcombe TE, Edelman MJ, Baker S Jr, Feliciano J, Novotny P, Hahn O, Crawford JA, Vokes EE. J Thorac Oncol. 2017 May;12(5):843-849. doi: 10.1016/j.jtho.2017.01.022. Epub 2017 Feb 1.

To learn about this trial, visit the ClinicalTrials.gov website at **https://clinicaltrials.gov/ct2/show/NCT00693992**

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.

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