Alliance Public Study Result Summary

What this study is about
This study measured a cancer treatment for patients with advanced non-small cell lung cancer who were at least 70 years old.

The full title of this study is: NCCTG (Alliance) N0821: A phase II first-line study of pemetrexed, carboplatin and bevacizumab in elderly patients with advanced nonsquamous non-small cell lung cancer with good performance status

Why the study was done
Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. Advanced NSCLC includes cancer cells in the lining around the lung (pleural effusion) or in other parts of the body. Common treatments for advanced stages of NSCLC include chemotherapy treatments, radiation, and other treatments that work on cancer markers in the body. Common treatment includes two chemotherapy drugs called carboplatin and pemetrexed (Alimta®).

Past studies showed that another drug called bevacizumab (Avastin®) helped some people with advanced NSCLC. Bevacizumab stops a protein in the body that affects how blood vessels form and function in cancers. It also has known side effects of increased blood pressure, and increased risk of bleeding or blood clots.

This study measured how effective and safe a combined cancer treatment was for patients with non-small cell lung cancer and who were at least 70 years old. The treatment included carboplatin, pemetrexed and bevacizumab.

Study results
These results are for advanced (stages IIIIB and IV) non-small cell lung cancer patients who are at least 70 years old and have decent health.

The study found that:
- 6 of 10 (60%) patients had stable lung cancer for at least 6 months.
- About half (average) of the patients lived over 1 year (13.7 months). This is called overall survival.
- The chemotherapy treatment did not lower the quality of life for these patients.

The most common serious side effects included:
- About 1 in 4 patients (26%) were very tired (fatigue). 
- About 1 in 10 patients (11%) had very low white blood count (neutrophils). 
- 3 patients had severe internal bleeding.

What the results mean
This means that the results did not reach the goal of controlling the cancer in at least 7 of 10 patients (70%) for at least 6 months.

How the study worked
All patients received the same treatment of carboplatin, pemetrexed, bevacizumab every 21 days for up to 6 cycles. After 6 cycles, they got treated with pemetrexed and bevacizumab once every 21 days until their cancer got worse or they had severe side effects that caused treatment to stop.

Here is a picture that explains how patients were treated.
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**REGISTRATION**

- Six 21-day cycles: Pemetrexed, carboplatin and bevacizumab

- If patient had complete response (CR), partial response (PR) or stable disease (SD), then more 21 day cycles of pemetrexed and bevacizumab

**When did the study start and end?** The study started in December 2008. All patients were enrolled by October 2010.

**How many patients joined?** 57 patients agreed to be in this study.

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

**Scientific publications about this study**
Details about the study can be found in these articles:

To learn about this trial, visit the ClinicalTrials.gov website at – [https://clinicaltrials.gov/ct2/show/NCT00798603?term=NCCTG+0821&rank=1](https://clinicaltrials.gov/ct2/show/NCT00798603?term=NCCTG+0821&rank=1)

This study was sponsored by the North Central Cancer Treatment Group, which is part of the Alliance for Clinical Trials in Oncology – a national cooperative network 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](http://www.allianceforclinicaltrialsinoncology.org).

*This summary lists what is known about this research study as of February 2015. New Information may be available.*

**We thank the people who joined this study and made it possible.** This study could have been completed faster if more people who had the opportunity to participate would have done so. If you know people who are offered the chance to join a cancer clinical trial, please encourage them to enroll. 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. We appreciate your advocating for federally-funded research to your elected representatives.