What this study is about

A cancer study that combined two drug treatments to treat people with brain tumors that have come back (a recurrence).

The official title of this study is: **NCCTG N0776 - Phase II trial of Avastin® in combination with sorafenib in recurrent glioblastoma multiforme (NCT00621686)**

Why the study was done

Glioblastoma is a kind of cancer in the brain. Cancer uses blood and blood vessels to grow. Some drugs affect blood vessels. One drug, called bevacizumab (Avastin®), is an approved treatment for people with glioblastoma. While it can help delay a return of cancer, the drug does not always help people live longer (called overall survival, or OS). Some past studies showed that another drug works on blood vessels in a different way, called sorafenib (Nexavar®). It might also work against glioblastoma.

This study looked at how these drugs worked in 54 patients with glioblastomas. The researchers studied how much the cancer shrank, how long the treatment worked (called response rate and progression-free survival (PFS)), and how long people lived. Researchers also measured proteins in each patient's blood (called biomarkers) to see if they could find groups of patients who did better with this kind of therapy. They also studied how side effects and treatment changed a person's quality of life.

The size of cancer in each patient's brain was measured several times with a test called MRI (magnetic resonance imaging). Blood was also collected over time to look for blood and gene markers that might show how the cancer cells reacted to the treatment.

Study results

These results are for people who are at least 18 years old and have glioblastoma that has come back (a recurrence).

The study found that:

- 10 of 54 patients (18.5%) had tumors shrink (response rate).
- 11 of 54 patients (20.4%) had a treatment response for at least 6 months (PFS6).
- About one-half of the patients were alive 6 months after treatment.
- Patient lived about the same amount of time Group A and Group B (see picture below).
- More biomarker studies are being done.

The most common serious side effects included:

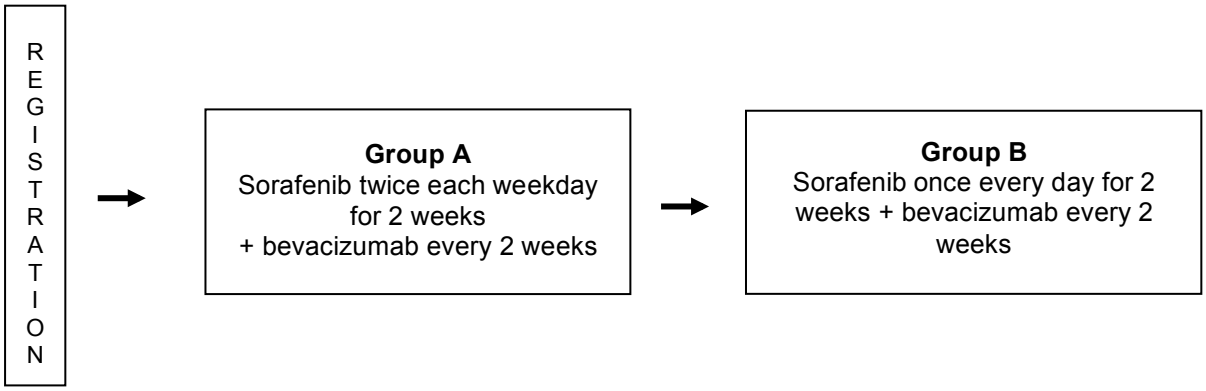
- 13 patients (24%) who got very tired (fatigue)
- 8 patients (15%) who got high blood pressure
- 7 patients (13%) who got a condition that causes a low level of salt (phosphorus) in the blood
- 5 patients stopped treatment due to severe side effects in Group A (26%), compared to 3 patients in Group B (about 16%).
- The dose of sorafenib was lowered for Group B because of side effects found in Group A.

What the results mean

This means the combined treatment of bevacizumab/sorafenib does not seem to be better than what would have been expected with bevacizumab alone for glioblastoma patients whose cancer has come back.

How the study worked

Here is a picture that explains how patients were placed into groups.



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

How many patients joined? 54 patients agreed to be in this study. 19 patients in Group A were given sorafenib twice each weekday (Monday through Friday), but serious side effects happened. 35 patients then joined Group B to get sorafenib once every day.

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:

- Phase II study of bevacizumab in combination with sorafenib in recurrent glioblastoma (N0776): A North Central Cancer Treatment Group trial
  Galanis E, Anderson SK, Lafky JM, Uhm JH, Giannini C, Kumar SK, Kimlinger TK, Northfelt DW, Flynn PJ, Jaeckle KA, Kaufmann TJ, Buckner JC
  Clin Cancer Res. 2013 Sep 1;19(17):4816-23. doi: 10.1158/1078-0432.CCR-13-0708. Epub 2013 Jul 5.
- NCCTG phase II trial of bevacizumab in combination with sorafenib in recurrent GBM
  Galanis E, Jaeckle KA, Anderson S, et al.
  J Clin Oncol 28 (Suppl 15): A-2018, 2010.

To learn about this trial, visit the ClinicalTrials.gov website at
http://clinicaltrials.gov/ct2/show/record/NCT00621686?term=n0776&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.

This summary lists what is known about this research study as of May 2014. 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.*