Alliance Public Study Result Summary
Study Number Alliance N0572

What this study is about

A cancer study that examines the best dose of sorafenib and temsirolimus in patients with glioblastoma that has returned.

The full title of this study is: Phase I/II of Temsirolimus and Sorafenib in Treatment of Patients with Recurrent Glioblastoma: North Central Cancer Treatment Group Study/Alliance N0572

Why the study was done

This study was done to determine a safe dose of sorafenib and temsirolimus and then testing the effectiveness of this combination in treating patients with recurrent glioblastoma, the most common and aggressive type of brain cancer.

There was a phase I and phase II portion to this study.

- The phase I portion of the study found the maximum tolerated dose, or the highest dose patients could have before experiencing significant side effects.
- The phase II portion of this study measured how long patients survived on treatment before their glioblastoma got worse.

Study results

These results are for people with recurrent glioblastoma.

The study did find a safe dose to treat patients (phase I study) but showed that it was not effective (phase II study). The goal of the study was to see if this treatment would delay the growth of the cancer and increase the length of survival, but we did not see that. Therefore, this study did not proceed to a phase III study.

The most common serious side effects in more than 6 out of every 100 patients (6%) included:

- 29 out of every 100 patients (29%) had fatigue
- 6 out of every 100 patients (6%) had decreased appetite
- 10 out of every 100 patients (10%) had muscle weakness
- One patient developed a hole in the intestine.

What the results mean

This means treating recurrent glioblastoma patients with a combination of sorafenib and temsirolimus did not increase the length of time their tumor remained stable before growing. A safe dose of the combination of sorafenib and temsirolimus was determined.

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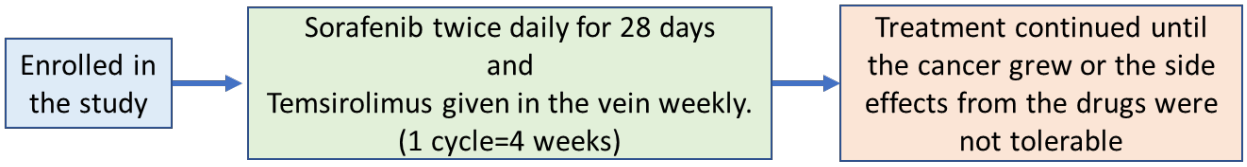
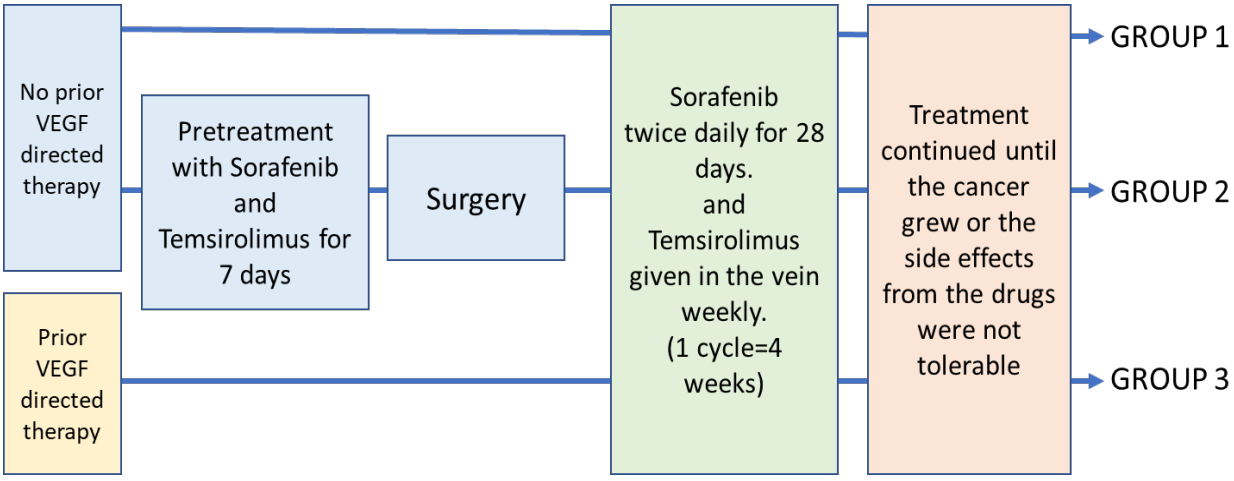
How the study worked

Phase I Study



Phase II Study



The phase I study observed patients treated with sorafenib and temsirolimus. The goal of this study was to determine the highest dose patients could be treated with before experiencing significant side effects.

The phase II study consisted of three study groups. Group 1 were patients who had never been treated with bevacizumab (VEGF directed therapy) and group 3 were patients who had been treated with bevacizumab. Group 2 were patients with a planned surgical biopsy or resection as part of their clinical care. Patients in group 2 received treatment 7 days prior to their surgery and resumed treatment after they recovered from their surgery. Patients were treated with the dose that was deemed tolerable in the phase I study.

When did the study start and end? The study started in March 2006. All patients were enrolled by December 2012.

How many patients joined? There were 12 patients in the phase I study and 103 (49 in group 1, 9 in group 2, and 45 in group 3) patients in the phase II study, for a total of 115 patients.

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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:

- Schiff, D. , Jaeckle, K. A., Anderson, S. K., Galanis, E. , Giannini, C. , Buckner, J. C., Stella, P. , Flynn, P. J., Erickson, B. J., Schwerkoske, J. F., Kaluza, V. , Twohy, E. , Dancey, J. , Wright, J. and Sarkaria, J. N. (2018), Phase 1/2 trial of temsirolimus and sorafenib in the treatment of patients with recurrent glioblastoma: North Central Cancer Treatment Group Study/Alliance N0572. Cancer, 124: 1455-1463. doi:10.1002/cncr.31219

To learn about this trial, visit the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/show/NCT00329719.

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 www.AllianceNCTN.org.

This summary lists what is known about this research study as of September 2019.

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.