What this study is about

A cancer study that combined two drugs together to treat people with glioblastoma, a kind of brain tumor

The official title of this study is: **NCCTG N0779 (Alliance) Phase II study of vorinostat (SAHA) in combination with bortezomib (PS-341) in patients with recurrent glioblastoma multiforme**

Why the study was done

One kind of cancerous brain tumor is called glioblastoma, known as GBM. People who have GBM are often treated with surgery, radiation, and drugs called chemotherapy. Only about half of these patients live at least 1½ year. Researchers are trying to find new ways to treat these patients so they can live longer.

Some research studies found that a drug called vorinostat (Zolinza®) helped fight cancer cells in patients with GBM. Other studies found that another drug called bortezomib (Velcade®) also helped fight cancer cells in GBM patients. Researchers combined these drugs in other cancers and those patients had better results with both drugs than when each drug was used by itself.

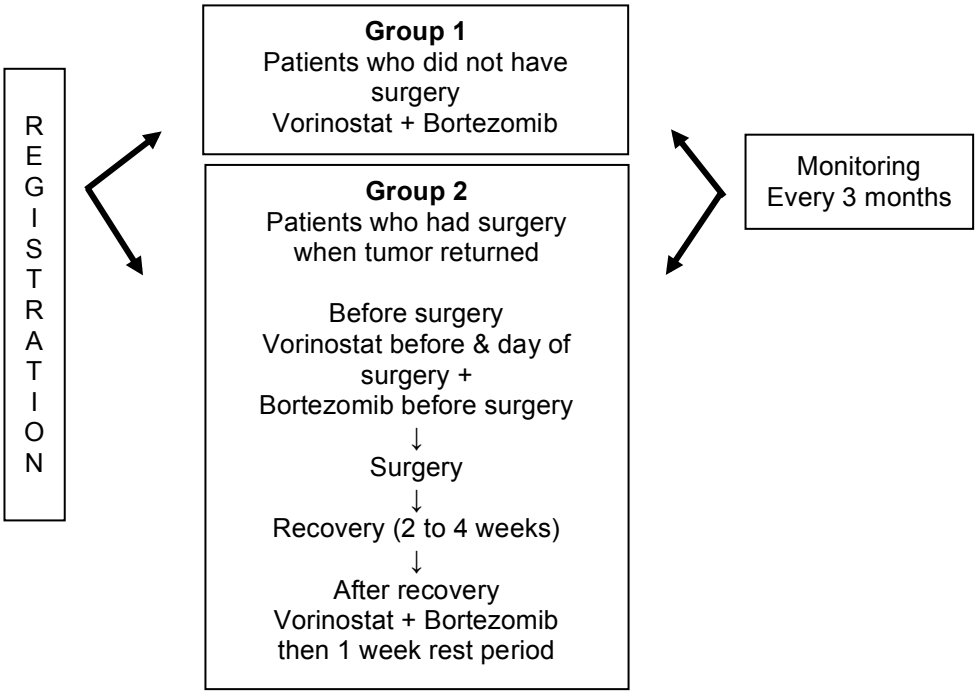
This study was done to learn if giving both of these drugs together would add time before cancer grew or came back. They also looked at tumor size, how long patients lived, and what side effects patients had.

Patients in this study had to be in fairly good health. Prior treatment was okay as long as there was at least one month since the last chemotherapy treatment and at least 2 months since radiation treatment. Patients who had major (severe) side effects received lower doses of the drugs. If that didn't work, they stopped taking these two drugs. Results were measured by taking pictures of the brain with a machine called magnetic resonance imaging (or MRI).

All patients in this study got this treatment every 3 weeks:

- Vorinostat (V) for 14 days, then 7 days off.
- Bortezomib (B) by i.v. 4 times in 11 days.

Here is a picture that explains how patients were placed into one of 2 groups.



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

How many patients joined? 37 patients who were at least 18 years old agreed to be in this study.

Study results

All patients had cancer that came back within 6 months and the study was closed.

- 25 patients received multiple treatment cycles. 14 of them (56%) had to get lower doses of the drugs due to side effects.
- Half the patients lived a little over 3 months. Some patients lived for over 2 years.
- One patient was still alive when the study was published in February 2012.
- Patients who received a drug called bevacizumab (Avastin®) before the study had their cancer return faster, and these patients lived a few months less than other patients.
- About 14 patients (37%) had some kind of major (severe) side effect.
- 2 patients (5%) left the study due to severe side effects

Severe side effects:

- 5 patients (14%) got very tired (fatigue)
- 2 patients (5%) got pain in their hands and feet (neuropathy)
- 11 patients (30%) had low platelets in the blood that can cause bleeding (thrombocytopenia)
- 2 patients (4%) had low white blood counts that can cause infection (lymphopenia)
- 2 patients (4%) had low white blood counts that can cause infection (neutropenia)
- Some patients had other side effects that were not as severe.

What the results mean

This means that the way these two drugs were used together is not suggested.

These results are for people at least 18 years old and whose glioblastoma has come back (recurred).

Scientific publications about this study

Details about the study can be found in these articles:

- Phase II trial of vorinostat in combination with bortezomib in recurrent glioblastoma: a north central cancer treatment group study
  Friday BB< Anderson SK, Yu C, Gianni C, Geoffroy F, Schwerkoske J, Mazurczak M, Gross H, Paion E, Jaeckle K, Galanis E
  Neuro-Oncology 2012 Feb;14(2):215-21. doi: 10.1093/neuonc/nor198. Epub 2011 Nov 16.

This study was sponsored by the North Central Cancer Treatment Group (NCCTG), 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 April 2014. New Information may be available.

Research studies (or clinical trials) are done to learn what treatments work better in people than what we already have. We thank the people who joined this study and made it possible. Their efforts have helped new patients diagnosed with cancer. Thank you for your interest in learning more about cancer research advances.