What this study is about

A study that compared two different drug treatments for patients who have melanoma that has spread to other parts of the body (called "metastatic") and cannot be removed with surgery.

The official title of this study is: NCCTG N0775 (Alliance)—A randomized phase II trial of temozolomide (TMZ) and Avastin or ABI-007/carboplatin (CBDCA) and Avastin in patients with unresectable stage IV malignant melanoma

Why the study was done

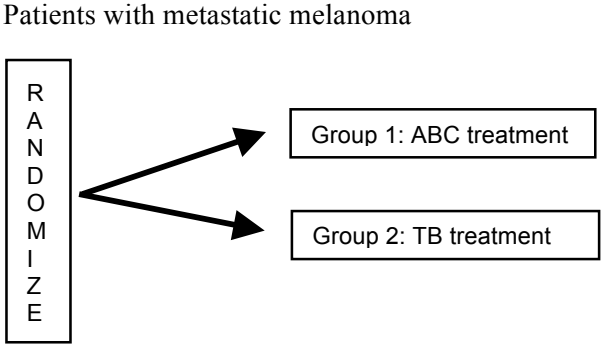
Melanoma that has spread to other parts of the body and cannot be removed with surgery is called "metastatic melanoma". Some newer drugs have been approved, but there is still much to learn about combining drugs for the best results. Bevacizumab (also called Avastin®) is a newer drug that stops cancer cells from growing by cutting off their blood supply. It has shown promise in metastatic melanoma when used with chemotherapy drugs.

This was a "phase II" study, which means it looked at how active treatment might be (called "efficacy"). Phase II studies are small. The goal of this phase II study was to see if two different drug treatments could shrink tumors safely. Patients with metastatic melanoma were assigned to receive one of the two different treatments. The treatments were not compared with each other. Side effects were also tracked, and they measured how many people had tumors that did not grow (called "progression-free survival" or PFS) in a 6-month period.

Half the patients were treated with three drugs called nab-paclitaxel, carboplatin and bevacizumab (called "ABC treatment"). The other half of patients were treated with two drugs called temozolomide and bevacizumab (called "TB treatment").

Patients were put into two groups by chance (randomized). This was done because no one knew if one treatment was better than another.

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



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

How many patients joined? 95 patients enrolled in this study.

Study results

Important findings:

For the 3-drug ABC (nab-paclitaxel, carboplatin and bevacizumab) treatment:

- The dose of the ABC treatment was lowered after 9 out of 28 patients (32%) had serious side effects.
- With the lower dose, serious side effects included low blood counts that raise the risk of infection, bleeding, feeling tired, and blood clots occurred less commonly. Some patients also had numbness and tingling in their hands and feet.
- 56 out of 100 patients (56.1%) who got the ABC treatment had tumors that did not grow for over 6 months after starting treatment, and they did not have any new tumors. On average, people on ABC treatment lived for 13.9 months. This means some people lived for a shorter time and some lived longer.

For the 2-drug TB (temozolomide and bevacizumab) treatment:

- Serious side effects in some patients included vomiting, being tired, low blood counts that raised the risk of infection, bleeding, and feeling tired. One person died from side effects that might have tied to the treatment.
- Almost 33 out of 100 patients (32.8%) who received the TB treatment had tumors that did not grow for 6 months after starting treatment, and they did not have any new tumors. On average people on TB treatment lived for 12.3 months. This means some people lived for a shorter time and some lived longer.

What the results mean

These results show that either of these chemotherapy treatments can be given to metastatic melanoma patients. Serious side effects can happen. A larger study that compares these two treatments for metastatic melanoma is suggested.

These results are for patients with melanoma that has spread to other parts of the body and can no longer be removed by surgery (metastatic).

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- A randomized phase 2 study of temozolomide and bevacizumab or nab-paclitaxel, carboplatin, and bevacizumab in patients with unresectable stage IV melanoma; A North Central Cancer Treatment Group study, N0775
  Kottschade LA, Suman VJ, Perez DG, et al.
  Cancer. 2013 Feb 1;119(3):586-592

This sheet reviews what is known about this research study as of November 2013. New Information may be available.

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. For more information about the Alliance, visit[*http://www.allianceforclinicaltrialsinoncology.org*](http://www.allianceforclinicaltrialsinoncology.org)

To learn more about this trial, visit the ClinicalTrials.gov website --
[*http://clinicaltrials.gov/ct2/show/study/NCT00626405?term=N0775&rank=1*](http://clinicaltrials.gov/ct2/show/study/NCT00626405?term=N0775&rank=1)

Research studies (or clinical trials) are done to learn what treatments work better in people than what we already have. Thank you for your interest in learning more about cancer research advances.