What this study is about

A study of a new drug treatment (chemotherapy) for patients with newly diagnosed lymphoma in the central nervous system (CNS), which is commonly in the brain and spinal cord

The official title of this study is: CALGB 50202 (Alliance) A phase II study of intensive chemotherapy and immunotherapy in patients with newly diagnosed primary CNS lymphoma

Why the study was done

Lymphoma is a kind of cancer that has cancer cells in the body's lymph system (part of the immune system). Primary central nervous system (CNS) lymphoma settles in the brain and spinal cord, and is one type of non-Hodgkin's lymphoma.

A common treatment for CNS was chemotherapy with whole-brain radiotherapy (high-energy radiation treatments for cancer). The radiotherapy had serious side effects in the brain, so doctors wanted to find a new treatment that worked as well, but had less side effects.

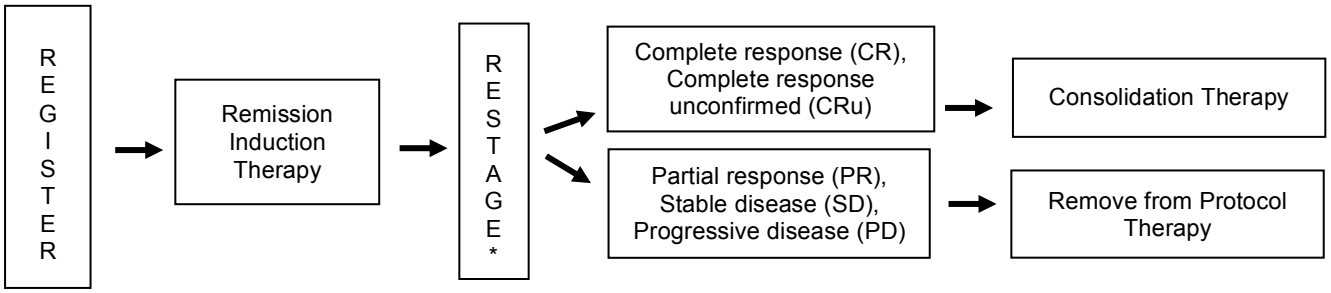
This study tested a new treatment for primary CNS lymphoma to see if cancer cells went away after the first treatment step called *induction therapy*. They also tested a mix of other drugs at high doses to see how they worked together and how long patients lived before their cancer came back (recurrence). Some cancer markers were also studied to see if they could find out which patients did better with the new treatment.

All patients in this study were given a mix of high-dose chemotherapy that was combined with an immune therapy drug called rituximab (Rituxan®). Immune therapy helps the patient's immune system to see tumor cells as strange to the body and removes them

Once patients were enrolled, they received induction therapy that included three drugs together. They were called methotrexate, temozolomide (Temodar®), and rituximab, known as MT-R.

Tests were run to see if their cancer responded to MT-R, called *complete response or CR*. If it did, patients then got two new drugs together called etoposide (Toposar®) and cytarabine (Cytosar-U®), known as EA. If their cancer did not respond to MT-R, they were done with the study.

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



* Patients will be assessed after 4 cycles of therapy. Patients who achieve a complete response or complete response unconfirmed will receive two cycles of consolidation therapy.

When did the study start and end? This study started in 2005. All patients were enrolled by November 2009.

How many patients joined? 44 patients agreed to be in this study.

Study results

Important findings:

- The new treatments had less side effects by avoiding whole-brain radiotherapy (WBR). High doses of WBR can kill brain cells and lead to a steady decline in how the body handles signals to and from the brain in patients. Many patients die from these side effects, instead of their cancer.

- Most patients on the study lived for 5 years after treatment was over, which was better than those on normally take WBR treatment..

- Patients on this study doubled the amount of time they lived without a return of their cancer, compared to patients in past studies who took WBR treatment.

- The new treatment was as effective in patients over 60 years old as it was in younger patients for the first time. This is important because CNS lymphoma is increasing in patients who are 65 and older.

- Patients who started the new treatment within a month after they were diagnosed did significantly better than those who did not get induction therapy in the first month.

- A cancer marker showed promise in helping to decide which treatment might work for certain patients, but more study is needed.

What the results mean

This means that chemotherapy combined with the immune therapy drug rituximab is a treatment option for patients with CNS lymphoma, including patients over 60 years old. This will help many patients avoid the side effects that come with whole-brain radiotherapy (WBR).

These results are for patients who are diagnosed with primary CNS lymphoma and have not had treatment.

You can talk with your doctor for more information.

Scientific publications about this study

Details about the study can be found in these articles:

- Rubenstein JL, His ED, Johnson JL, Jung S, Nakashima MO, Grant B, Cheson BD, Kaplan LD. Intensive Chemotherapy and Immunotherapy in Patients With Newly Diagnosed Primary CNS Lymphoma: CALGB 50202 (Alliance 50202). *Journal of Clinical Oncolog* 2013 31(25): 3061-3068.

This sheet reviews what is known about this research study as of February 2014. New Information may be available.

This study was sponsored by the Cancer and Leukemia Group B (CALGB), 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.

To learn more about this trial, visit the ClinicalTrials.gov website -- http://clinicaltrials.gov/ct2/show/NCT00098774?term=CALGB+50202&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.