The Radiation Therapy Oncology Group, together with the Eastern Cooperative Oncology Group (ECOG), the North Central Cancer Treatment Group (NCCTG) and the Southwest Oncology Group (SWOG) are national cancer research organizations sponsored and funded by the National Cancer Institute (NCI). These clinical trial groups are made up of the leading medical facilities in the United States and Canada. For over 40 years these groups have played a key role in the development of new treatments for cancer.

The Radiation Therapy Oncology Group, known as RTOG, sponsors cancer clinical trials. The goal of the RTOG is to increase survival and improve quality of life for patients diagnosed with cancer. RTOG has partnered with three other cancer clinical trial groups to recruit patients to this study.

The data collection, statistical and administrative offices for this study are located at the RTOG Headquarters in Philadelphia, Pennsylvania. The RTOG is a project of the American College of Radiology, Reston, Virginia.

For additional information about RTOG contact:
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RTOG/ECOG/NCCTG/SWOG Protocol 98-13

A Phase I/III Randomized Study of Radiation Therapy &Temozolomide versus Radiation Therapy & BCNU for Anaplastic Astrocytoma (IND#60,265)

STUDY CHAIRS

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MALIGNANT BRAIN TUMORS

RTOG Protocol 98-13

A Study to Determine if the Investigational Drug Temozolomide is Better than the Standard Treatment for Anaplastic Astrocytoma Brain Tumors

Information for Participants

Radiation Therapy Oncology Group

in conjunction with

Southwest Oncology Group
A National Cancer Research Group

NCCTG
North Central Cancer Treatment Group

Your doctor has determined that you have a malignant (cancerous) brain tumor. Standard treatment for this kind of tumor is surgery followed by radiation to the tumor site. Chemotherapy with the drug BCNU is also usually given during radiation therapy and for the next year.

Although standard treatment may delay your tumor from growing back, possibly for many years, this kind of tumor eventually returns in many patients. Also BCNU can damage your blood cells and lungs. Because of this, researchers continue to look for better treatments for this type of cancer.

One treatment under investigation is the use of the investigational chemotherapy drug Temozolomide given together with radiation therapy.

Your doctor would like you to consider participating in a nationwide research study to see if using Temozolomide, instead of BCNU, can prevent or delay the return of your tumor and have less side effects.

Your institution is one of the major cancer centers in North America participating in this study. Approximately 460 people will take part in this trial.

Your participation in this study is entirely voluntary. If you are interested in participating or have any additional questions please talk to your doctor.

Frequently Asked Questions

What is a clinical trial?

A clinical trial is an organized study involving a large group of patients. The goal of the trial is to obtain a large amount of information so that the treatments being studied can be evaluated in a scientific manner.

Why am I a candidate for this study?

In addition to having a malignant brain tumor called anaplastic astrocytoma or oligodendroglial/astrocytoma, there are other eligibility requirements to participate in this study. Your doctor has determined that you meet these requirements and that you might benefit from participating in this study.

What treatment will I receive?

Patients will be randomly assigned to one of two treatment groups. The first group will receive the standard treatment of surgery, radiation and BCNU chemotherapy. The second group will also undergo surgery and radiation but they will receive the investigational drug Temozolomide for chemotherapy.

Which treatment will I receive?

You will be randomly assigned by a computer at the RTOG Headquarters to receive either BCNU or Temozolomide. Neither you nor your doctor can choose which treatment you will receive. However you both will know which drug is assigned.

Are there side effects?

For the most part, no severe side effects are likely although unexpected problems can occur. There are side effects commonly associated with radiation therapy and chemotherapy that are a part of routine cancer care. These, and all other potential side effects, are fully explained in the study informed consent form.

How often will I be seen?

- Radiation is given 5 days a week for 6 weeks.
- If you receive Temozolomide you will be given capsules to take for 5 days in a row, every 4 weeks for 1 year.
- If you receive BCNU it will be given by vein (intravenously) as an outpatient for 3 days in a row, every 8 weeks for 1 year.
- You will have routine follow-visits with your doctor. At each visit you will be asked to complete a short questionnaire about your mental status.

How much will it cost?

If you are assigned to receive Temozolomide it will be supplied to you at no cost. Other treatment costs for this study are generally considered part of normal cancer care and will be billed to your insurance carrier. Expenses not covered by your insurance or Medicare may be billed to you.