

Bevacizumab

for Patients with GLIOBLASTOMA

RTOG Research Study

Does the addition of bevacizumab to radiation therapy and temozolomide improve outcome for patients with glioblastoma?

The standard treatment for patients with glioblastoma, a cancerous brain tumor, is radiation therapy plus temozolomide followed by further treatment with temozolomide.

The goal of this research study is to find out if adding bevacizumab to radiation therapy and temozolomide will improve the outcome for patients with glioblastoma and to find out the other effects, good and/or bad, this therapy has on patients. Bevacizumab is a drug that can interrupt the body's ability to grow new blood vessels, causing tumors to shrink.

Many institutions worldwide are participating in this trial sponsored by the RTOG. Approximately 720 patients are expected to take part in this study.

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

The Radiation Therapy Oncology Group, known as RTOG, is a national cancer research organization funded by the National Cancer Institute. RTOG member investigators come from over 300 of the leading academic and community medical facilities in the United States, Canada, and internationally.

RTOG has played a key role in the development of new cancer treatments for over 40 years. The goal of the group is to increase survival and improve the quality of life for patients diagnosed with cancer.

RTOG receives National Cancer Institute funding as well as corporate support.

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**See the next page for
more information about this study.**

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Phase III Double-Blind Placebo-Controlled Trial of Conventional Concurrent Chemoradiation and Adjuvant Temozolomide Plus Bevacizumab Versus Conventional Concurrent Chemoradiation and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma

Frequently Asked Questions

What is a clinical trial?

Clinical trials are research studies that look for better ways to prevent, diagnose, or treat disease.

Who can join this study?

In addition to having glioblastoma, there are other eligibility requirements to participate in this study. Your doctor can determine if you meet these requirements.

What are the possible treatments?

All patients receive six weeks of radiotherapy (RT) while taking the drug temozolomide (TMZ) once every day in capsule form. During the fourth week of RT patients will start receiving an IV treatment containing either bevacizumab (BEV) or placebo once every other week. TMZ and BEV/placebo treatments will continue for up to one year.

Diagnosis of Suspected Brain Tumor



Brain Tumor **Surgery** - Tissue Sent to Central Site for Evaluation



Start Treatment

- TMZ capsules daily + RT 5 days per week for 3 weeks



Randomly Assigned Treatment Begins

- IV **Placebo** (Group 1) or IV **BEV** (Group 2) every other week for 12 months.
- TMZ capsules daily + RT 5 days per week continues for 3 more weeks.
- When RT ends TMZ continues for 5 days every 4 weeks while receiving BEV or Placebo.

Patients are randomly assigned to receive either BEV or placebo through the use of a computer program. Neither you nor your doctor will know which group you are assigned. Overall, you will have an equal chance of being placed in either group. However, during the initial enrollment into the study, a higher

percentage of patients will be enrolled on the treatment that includes BEV (Group 2).

Subsequently, a higher percentage of patients will be enrolled on the treatment that includes placebo (Group 1) in order to balance enrollment. Once enrollment is balanced between the two groups, you will have an equal chance of being placed in either group.

Are there side effects?

Possible risks for patients who receive radiotherapy for brain tumors include scalp redness or soreness, hair loss, ear/ear canal reactions, lethargy, fatigue, and temporary aggravation of brain tumor symptoms such as headaches, seizures, or weakness. Possible risks of temozolomide include nausea and/or vomiting, decreased appetite, headache, constipation, drowsiness/fatigue, inability to sleep and hair loss. Possible risks for patients receiving bevacizumab include nose bleeds, high blood pressure, fatigue, rash, headache, and soreness in the mouth or throat. Your doctor will review all of the side effects.

How often will I be seen?

You will receive radiation plus temozolomide for a maximum of 7 weeks. Intravenous treatment will start at the beginning of the fourth week of radiation along with temozolomide. You will receive the I.V. bevacizumab or placebo and take the temozolomide for up to 12 months following the end of radiation. You will then be asked to return for follow-up visits on a regular basis. We will keep track of your medical condition for the rest of your life..

How much will it cost?

The treatment costs for this study are generally considered part of normal cancer care and will be billed to your insurance carrier. As with all cancer therapies, expenses not covered by your insurance or Medicare may be billed to you. The bevacizumab or placebo will be provided at no cost to you.