Can a second chemotherapy drug in addition to standard radiation and temozolomide extend your life or prevent the growth and spread of your brain tumor?

NRG ONCOLOGY

Advancing Research. Improving Lives.™

Visit the patient webpage for this study:

ABOUT THE TRIAL

NRG-BN011 is a clinical study for people with a type of brain tumor called a glioblastoma that have not yet received treatment other than surgery for their disease. Participants in this trial will need to be tested to see if their tumor has a biomarker called "methylated" MGMT. A biomarker gives information about how the tumor may respond to treatment. The MGMT methylation test helps predict if the tumor will respond to temozolomide, the standard chemotherapy drug used for glioblastomas. MGMT methylated tumors are more likely to respond to temozolomide chemotherapy. NRG-BN011 will test to see if the addition of a second chemotherapy drug called lomustine to the usual treatment of radiation and temozolomide chemotherapy can help extend your life or stabilize your cancer. Lomustine is currently approved by the Food and Drug Administration (FDA)- to treat brain tumors, however, it is usually used for recurrent tumors. Researchers are doing this study to find out if this approach is better, the same, or worse than the usual approach for your brain tumor.

VERSION DATE: 2/17/2025

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on sex-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org

Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
People over the age of 18 with a type of brain tumor called a glioblastoma that has the biomarker called “methylated” MGMT who have not yet received treatment for their disease other than surgery.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments?
If you decide to take part in this study, your study doctor will use some of the tissue removed during your surgery to confirm that your tumor is a glioblastoma and to see if the tumor has the methylated MGMT biomarker.
If you have a confirmed methylated MGMT glioblastoma, you will be randomly assigned to one of two study groups. Treatment Group 1 will receive the usual treatment for glioblastoma of radiation therapy and temozolomide chemotherapy. Treatment Group 2 will receive radiation therapy and a combination of the chemotherapy drugs lomustine and temozolomide. You will have an equal chance of being in Group 1 or Group 2.

How long will I be in this study?
If you are in Group 1 receiving the usual treatment of radiation and temozolomide chemotherapy), you will receive radiation and chemotherapy together for 6 weeks, followed by temozolomide alone every 4 weeks for up to 6 months.
If you are in Group 2 receiving radiation and the combination of lomustine and temozolomide chemotherapy, you will receive radiation for 6 weeks plus both chemotherapy drugs every 6 weeks for up to 9 months.

Are there side effects?
There may be some. The most common side effects of temozolomide include headache, seizure, constipation, nausea, vomiting, diarrhea, trouble with memory, difficulty sleeping, muscle weakness, paralysis, difficulty walking, dizziness, tiredness, or hair loss. The most common side effects of lomustine include infection, bruising or bleeding, anemia, sores in the mouth, nausea, vomiting, or hair loss. Some of the most common side effects of radiation to the brain include reddening, tanning, or peeling of skin, scalp soreness, hair loss, tiredness, lethargy, ear or ear canal reactions, and temporary aggravation of brain tumor symptoms such as headaches, seizures, or weakness. Your doctor will review all potential side effects with you.

MORE INFORMATION

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer.
You may also call: 1-(800)-4-CANCER (1-800-422-6237).