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 gender-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.

NRG Oncology Clinical Trial: NRG-BN007

Protocol NRG-BN007, A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab Versus Temozolomide in Patients With Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma (NCT 04396860)

About the trial

NRG-BN007 is a clinical study that replaces the usual treatment of chemotherapy with immune therapy treatment for people who have a type of brain tumor called a glioblastoma and a tumor biomarker called “not methylated” or “unmethylated” MGMT. A biomarker is a change in the tumor’s genes that gives information about how the tumor may respond to treatment. Typically, people with this type of brain tumor undergo surgery to remove the tumor followed by radiation therapy and a Food and Drug Administration (FDA)-approved chemotherapy drug called temozolomide. Additionally, some patients also use an FDA-approved wearable device called Optune to accompany the usual treatment, which uses electrodes applied to the patient's head to send electric signals that could slow or stop cancer cell growth. NRG-BN007 was designed to determine if replacing the chemotherapy drug temozolomide with the immune therapy drugs ipilimumab and nivolumab can help lengthen the time without the brain tumor growing or returning and extend the life of patients who have a glioblastoma when compared to the usual treatment approach. Immune therapy drugs, or immunotherapy, stimulate or suppress the immune system to allow the body to fight the cancer.

Can immune therapy help extend the life of people with a glioblastoma (brain tumor)?
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?
Men and women 18 and older who have a glioblastoma that has the unmethylated MGMT biomarker and who have not yet received treatment.

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 study treatments?
If you decide to take part in the study, you will be assigned by chance to one of two treatment groups.

Patients assigned to group one will get the usual treatment approach of radiation therapy combined with temozolomide chemotherapy followed by further temozolomide chemotherapy when the radiotherapy treatment ends. Patients in group one also have the option of using the Optune device. Patients assigned to group two will receive radiation therapy combined with the immune therapy drugs ipilimumab and nivolumab. Patients in group two will continue to receive the immune therapy drugs when the radiation treatment ends.

How long will I be in this study?
If you are assigned to group one, you will receive chemotherapy every day for approximately 6 weeks and, during this time, you will also receive radiation therapy 5 days per week for the 6 weeks. Beginning 1 month following radiation therapy, you will receive chemotherapy 5 days in a row every 4 weeks for up to 12 months. Temozolomide, the chemotherapy drug, will be taken by mouth.

If you are assigned to group two, you will receive radiation therapy 5 days per week for 6 weeks plus the immune therapy drug ipilimumab by vein every 4 weeks for 4 times and nivolumab by vein every 2 weeks. Both ipilimumab and nivolumab treatment will start the first day you start radiotherapy. You will continue to receive nivolumab every 2 weeks for as long as you seem to benefit from it.

After you finish your treatment, your doctor and study team will watch you for side effects and continue to evaluate your disease.

Are there side effects?
There may be some. The radiation therapy treatment and chemotherapy and immune therapy drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. Some common side effects of the chemotherapy drug used in this study include headaches, trouble with memory, nausea or vomiting, muscle weakness, difficulty sleeping, and more. A common side effect of nivolumab is tiredness. Some common side effects of ipilimumab include skin problems such as itching, rash, hives, and blisters, tiredness, diarrhea, nausea, and more. Some common side effects of radiation therapy to the brain include hair loss, reddening of the skin, tiredness, lethargy, and more. Your doctor will review all of the 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).