NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG). The research network seeks to carry out clinical trials with emphases 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 comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses more than 1,300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.

NRG Oncology Clinical Trial BN003
Phase III Trial of Observation Versus Irradiation for a Gross Totally Resected Grade II Meningioma

About the trial
A common approach to treating newly diagnosed, surgically removed grade II meningioma is to observe a patient after surgery and only treat the patient with radiation if the tumor comes back. For patients managed in this fashion, about 50-75% are free of meningioma at three to five years. Radiation therapy given after surgery may decrease the risk of the tumor growing back. NRG-BN003 will evaluate the good and bad effects of using radiation to treat a meningioma that has been completely removed by surgery before the tumor returns to see if this treatment is better, worse, or equal to the usual approach. To be considered successful, the use of radiation should safely improve the likelihood that the tumor does not grow back by at least 15% at 3 years as compared to surgery alone.

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Can Radiation Therapy Following Surgery Improve Outcomes for Grade II Meningioma?
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?
In addition to having newly diagnosed, surgically removed grade II meningioma, there are other eligibility requirements to participate in this study. Your doctor can determine if you meet these requirements.

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?
NRG-BN003 randomly assigns patients to one of two study groups. Group 1 will be observed following surgery, without radiation treatment. Group 2 will receive radiation therapy to the area of the brain where the meningioma was removed, with careful attention to minimizing the amount of radiation received by normal tissue.

How long will I be in this study?
If you are in Group 2, you will receive radiation therapy 5 days per week for up to 6.5-7 weeks for a total of 33 treatments. After you finish radiation, your doctor will continue to watch you for side effects and follow your condition through office visits at months 3, 6, and 12 for the first year. In years 2 and 3, your doctor will observe your conditions every 6 months, and then one a year for 10 years after. Participants assigned to Group 1 will be closely followed by their doctor through office visits at the same intervals as the patients who received radiation therapy. Patients in both groups will have MRIs at least every 6 months for 5 years, and then once a year for 10 years.

Are there side effects?
Side effects from the treatment of meningiomas depend largely upon the location of the tumor. Possible side effects of radiation therapy include scalp redness or soreness, hair loss which may be temporary or permanent, temporary hearing decrease or loss, tiredness, temporary increase of brain tumor symptoms such as headaches, seizures, or weakness. More serious and less common side effects include nausea, vomiting, dry mouth or changes in taste, decreased ability to concentrate, among others. The type and likelihood of possible side effect varies considerably by size and location of the meningioma, and your doctor will review all of the potential side effects carefully with you.

More Information
You may visit the NCI website at cancer.gov for more information about studies or general information about cancer.

You may also call the NCI Cancer Information Service to get the same information at 1-(800)-4-CANCER (1-800-422-6237)