Testing proton craniospinal radiation therapy versus the usual radiation therapy for leptomeningeal metastasis

NRG ONCOLOGY

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Visit the patient webpage for this study:

ABOUT THE TRIAL

NRG-BN014 is a clinical study for people with breast cancer or non-small cell lung cancer that has spread to the cerebrospinal fluid-filled space that surrounds the brain and spinal cord, also called leptomeningeal metastasis (LM). This study will compare two types of radiotherapy, proton craniospinal radiation therapy and photon involved-field radiation therapy. Proton craniospinal radiation therapy is a type of radiotherapy that uses proton particles to deliver radiation, in this case, to your entire cerebrospinal fluid-filled space surrounding your brain and spinal cord where the LM is located. Photon involved-field radiation therapy uses x-rays to treat specific areas where LM is present to relieve and/or prevent symptoms. Researchers want to know if using proton craniospinal radiation therapy to treat the entire cerebrospinal fluid-filled space is better, worse, or the same as the usual treatment (photon involved-field radiation therapy) for people with your type of cancer.

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 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

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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 with breast cancer or non-small cell lung cancer that as spread to the cerebrospinal fluid filled space that surrounds the brain and spinal cord (leptomeningeal metastasis).

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, you will be randomly assigned to one out of two potential study groups. Study Group 1 will receive photon involved-field radiation therapy, which is the usual type of treatment for this type of cancer. You will get radiation to specific areas of LM that are causing and/or may cause symptoms. Study Group 2 will receive proton craniospinal radiation therapy to the entire space containing the cerebrospinal fluid, brain, and spinal cord where LM is located. Both groups will receive radiation therapy 5 days a week for a total of 10 days of treatment.

How long will I be in this study?
After you finish your treatment, your doctor and study team will watch you for side effects. They will check you every 3 months for 1 year, then every 6 months for 1 year. These visits may be in-person or by telehealth. After 2 years, your study doctor will check in with you and continue to follow your condition approximately every 6 months for the next 3 years, but this will not require an in-person doctor visit. This means your study doctor will follow you for 5 years after your treatment.

Are there side effects?
There may be some. Proton and photon radiation therapy both may include side effects. Most commonly these include skin changes, hair loss, tiredness, weakness, dry mouth, problems thinking clearly, infection, bruising or bleeding, and anemia. 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).