NRG Oncology Clinical Trial: NRG-GI006

Phase III Randomized Trial of Proton Beam Therapy (PBT) versus Intensity Modulated Photon Radiotherapy (IMRT) for the Treatment of Esophageal Cancer

About the trial

NRG-GI006 is a clinical trial that is studying proton therapy to see if this treatment does or does not improve survival and decrease side effects when compared to the current usual treatment for people with esophageal cancer. Typically, the usual treatment for people who have this type of cancer is a combination of chemotherapy and photon radiation therapy followed by surgery. Proton therapy is a type of radiation therapy that uses protons, or positively charged particles, rather than x-rays to treat cancer. Both photon (x-ray) and proton therapies precisely deliver radiation to the tumor without damaging much of the tissue around it and have been tested for safety; however, researchers want to know if one of the treatments works better than the other or if the treatments work equally well.

ClinicalTrials.gov Identifier: NCT01512589

About NRG Oncology

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of people with cancer. 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 comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses 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 215-854-0716 or email info@nrgoncology.org.
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 who have esophageal cancer who are deemed eligible for the combined chemotherapy and radiation therapy treatments.

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?
Participants on this trial will be randomly assigned to one of two possible study groups. Group 1 will receive proton radiation therapy with the usual chemotherapy. Group 2 will receive photon radiation therapy along with the usual chemotherapy. If eligible for surgery, participants in both groups will receive surgery to remove their cancer 4-8 weeks after radiation and chemotherapy treatment.

How long will I be in this study?
Groups 1 and 2 will both receive radiation and chemotherapy for approximately 6 weeks. 4-8 weeks after the completion of chemotherapy and radiation, participants will have their cancer surgically removed if they are a candidate for surgery. Your doctor will check in with you every 3 to 6 months for up to 3 years following treatment, then once a year for the rest of your life to follow your condition and watch for side effects.

Are there side effects?
There may be. Some of the most common side effects of radiation (proton and photon) that the study doctors know about are swelling and redness or narrowing of the esophagus, tiredness, and nausea. Some of the most common side effects of carboplatin and paclitaxel chemotherapy that doctors know about include itching or rash, tiredness, nausea and vomiting, mouth sores, and hair loss. Your doctor will review all of the potential side effects with you.

Frequently Asked Questions

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)