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.

NRG Oncology Clinical Trial: NRG-HN004

Randomized Phase II/III Trial of Radiotherapy with Concurrent MEDI4736 (Durvalumab) vs. Radiotherapy with Concurrent Cetuximab in Patients with Locoregionally Advanced Head and Neck Cancer with a Contraindication to Cisplatin

About the trial

NRG-HN004 is a clinical trial that is comparing any good and bad effects of usual radiation plus the study treatment, MEDI4736 (durvalumab), to the usual therapy of radiation plus cetuximab, in patients with head and neck cancer who cannot take the chemotherapy drug cisplatin. Durvalumab is an immunotherapy that works by boosting your immune system to help recognize and fight cancer. It is FDA approved for cancer of the urinary system, but it is not approved for use with radiation therapy in head and neck cancer. Cetuximab, the usual treatment, is an antibody therapy. This study will allow the researchers to know whether the different approach (radiation plus durvalumab, the immune therapy) is better, the same, or worse than the usual approach (radiation plus cetuximab, the antibody therapy).

This is the phase II and III section of the study. The “lead-in” phase looked at the potential side effects of combining durvalumab with radiation.

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To contact NRG Oncology, call 215-854-0716 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 who have advanced head and neck cancer who cannot take cisplatin, a standard chemotherapy drug. Your doctor can determine if you meet these and other 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?
The study has two groups. Each group will receive radiation therapy and an anti-cancer drug. Group 1 will receive 1 dose of cetuximab 1 week before the start of radiation therapy and then radiation plus weekly cetuximab for 7 weeks (the usual treatment for your head and neck cancer). Group 2 will receive radiation therapy for 7 weeks (part of the usual treatment for your head and neck cancer) and durvalumab. The first dose of durvalumab will be given 2 weeks before radiation therapy begins, the second dose given 3 weeks after the first dose, then all remaining doses given every 4 weeks for a total of 7 doses.

How long will I be in this study?
Group 1 will receive treatment for a total of 8 weeks. Group 2 will receive treatment for around 24 weeks. After you finish treatment, your doctor will continue to watch you for side effects and follow your condition every 4 months for 1 year, every 6 months for 2 years, and then every year.

Are there side effects?
Both radiation therapy and anti-cancer drugs may cause side effects. Your doctor will review all of the potential side effects with you. You are encouraged to tell the study doctor if you notice or feel anything different so that the doctor can see if you are having a side effect. The study doctor may be able to treat some side effects and may adjust the study drugs to try to reduce side effects.

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) 1-(800)-4-CANCER (1-800-422-6237)