NRG Oncology Clinical Trial: RTOG 1216

Randomized Phase II/III Trial of Adjuvant Radiation Therapy with Cisplatin, Docetaxel-Cetuximab, or Cisplatin-Atezolizumab in Pathologic High-Risk Squamous Cell Cancer of the Head and Neck

NCT01810913

About the trial

NRG-RTOG-1216 is a clinical study that is testing two different types of drug therapy combined with radiation for people receiving treatment after their surgery for high-risk head and neck cancer. This study has two parts and the first part of the study has already been completed. The initial results showed that the chemotherapy drugs docetaxel and cetuximab given with radiation therapy is better than docetaxel alone with radiation therapy in controlling high-risk head and neck cancer. In the second part of the study, which is now seeking volunteers, doctors want to learn if docetaxel and cetuximab with radiation therapy or cisplatin plus the immunotherapy drug, atezolizumab, with radiation therapy is better than the usual approach to treating HPV-negative head and neck cancer. The usual approach for patients who are not in a study is the combination of cisplatin chemotherapy and radiation therapy. As an immunotherapy drug, atezolizumab is different from the other drugs in the study in that it works by stimulating the body’s own immune system to fight cancer instead of directly attacking cancer cells. It is approved by the U.S. Food and Drug Administration to treat other cancers, but not head and neck cancer. Doctors want to learn if atezolizumab could be helpful for treating high-risk head and neck cancer and this is one of the reasons why this second part of the study is being conducted.

Is radiation with docetaxel and cetuximab or radiation with cisplatin and atezolizumab better than usual therapy for high-risk head and neck 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.
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?
Men and women 18 and older, who have a proven diagnosis of head and neck squamous cell carcinoma involving the oral cavity (excluding lips), oropharynx (p16 negative), larynx, or hypopharynx, may be eligible for the study.

Can I change my mind if I choose to take part in this study?
Yes. Taking part in this study is voluntary. 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?
Trial participants will be randomly assigned to one of three possible treatment arms.
- Patients assigned to treatment arm 1 will receive the usual approach consisting of radiotherapy for 5 days a week over a 6 week period with cisplatin chemotherapy once a week during the 6 weeks of radiotherapy.
- Patients assigned to treatment arm 2 will also receive radiotherapy for 5 days a week over 6 weeks, but patients on this treatment arm will receive docetaxel chemotherapy once a week for 6 weeks and cetuximab starting 1 week before radiotherapy. Patients on treatment arm 2 will also receive cetuximab once a week for during the 6 weeks of radiotherapy.
- Patients assigned to the third treatment arm will receive radiotherapy with cisplatin chemotherapy once a week for 6 weeks. Patients on treatment arm 3 will also receive atezolizumab 1 week before radiotherapy and then every 3 weeks for 21 weeks. Atezolizumab is the immunotherapy drug that is approved for other types of cancers, but not your type of cancer.

How long will I be in this study?
After you finish radiotherapy, which takes approximately six weeks, your doctor and study team will watch you for side effects. They will check you one month after treatment, three months after treatment, and every three months for two years after treatment. After two years, they will check you every six months for three years and then every year for life.

Are there side effects?
There may be some. There is a risk that you could have side effects from the study approach. These side effects may be worse and may be different than you would get with the usual approach for your cancer. Some of the most common side effects that the study doctors know about are: infection; nausea and vomiting; diarrhea; pain; tiredness; kidney problems; numbness/tingling in hands and feet. There may be some side effects that the study doctors do not yet know about. 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).