

Comparing radiation plus cetuximab to radiation plus chemotherapy in people with advanced head and neck cancer who cannot receive cisplatin

NRG
ONCOLOGY

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webpage for this
study:



NRGOncology.org/CONCISE

ABOUT THE TRIAL

NRG-HN016, also known as the “CONCISE” study, is a clinical trial comparing two usual approaches for people who have advanced head and neck cancer and are unable to take the chemotherapy drug cisplatin. Typically, patients with this type of cancer are treated with radiation therapy combined with either chemotherapy, such as carboplatin and paclitaxel, or an anti-cancer drug such as cetuximab. For patients who receive the usual approach, about 35 out of 100 are free of cancer after 2 years. The NRG-HN016 trial will be comparing both of these usual treatments for your type of cancer.

This study will help the study doctors find out if the usual approach of radiation and chemotherapy is better, the same, or worse than the usual approach radiation and cetuximab. To decide if it is better, the study doctors will be looking to see if the radiation and chemotherapy approach will increase the number of patients without their disease getting worse after 2 years from about 63 out of 100 with radiation and cetuximab, to 73 out of 100 with radiation and chemotherapy.

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 sex-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?

People who have advanced head and neck cancer and are unable to receive one of the standard chemotherapy treatments called cisplatin.

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 either get the usual radiation therapy plus cetuximab for 8 weeks, or you will get the usual radiation therapy plus carboplatin and paclitaxel chemotherapy for 7 weeks.

How long will I be in this study?

After you finish your treatment, your doctor and study team will continue to follow your condition and watch you for side effects. They will check you at 4 months, 6 months, and then every 6 months up until year 3 after you finish treatment. After that, they will continue to follow your condition annually for your lifetime.

Are there side effects?

There may be some. Some of the most common side effects that the study doctors know about are: mouth sores, diarrhea, nausea, vomiting, and low blood counts that may cause infection or tiredness. There may be some risks 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).