NRG Oncology Clinical Trial: NRG-HN007

An Open-Label, Phase III Study of Platinum-Gemcitabine with or Without Nivolumab in the First-Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma

About the trial
NRG-HN007 is a clinical study that aims to determine if adding the immune therapy drug nivolumab to the usual chemotherapy treatment can help extend life expectancy for patients with nasopharyngeal cancer that has recurred or spread outside the nasopharynx. Typically patients who have this type of cancer are treated with the chemotherapy drugs cisplatin (or carboplatin) and gemcitabine. Approximately 56 out of 100 patients who receive the usual chemotherapy treatment are alive after 2 years. NRG-HN007 was created to see if adding nivolumab to the usual approach provides a better outcome as there is evidence to support the drug is effective in shrinking your type of cancer. There is no way to know if the study drug will extend your life compared to the usual approach for your type of cancer, however, this study will be able to help study doctors learn things that will help people with your type of cancer in the future.

Doctors on this study will also ask you to fill out surveys to assess your quality of life regarding your ability to swallow, your physical, and your emotional well-being before, during, and after treatment.

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.

Will adding an immune therapy drug to standard chemotherapy extend the life of patients with nasopharyngeal cancer?
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 recurrent or metastatic nasopharyngeal cancer.

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?
If you decide to take part in the study, you will be assigned by chance to one of two treatment groups. Patients assigned to group one will get the immune therapy drug nivolumab plus the usual chemotherapy drugs used to treat this type of cancer: cisplatin (or carboplatin) with gemcitabine. Patients assigned to group two will get the usual chemotherapy drugs alone for this type of cancer.

How long will I be in this study?
Patients assigned to both group one and group two will receive the chemotherapy drug cisplatin (or carboplatin) through a vein on day 1 of each cycle and the chemotherapy drug gemcitabine through vein on day 1 and 8 of each cycle. All patients will receive 6 cycles and each cycle lasts 21 days. Patients assigned to group one will also receive the additional drug nivolumab through a vein on day 1 of each cycle and may receive nivolumab for up to 2 years.

After you finish your treatment, your doctor and study team will watch you for side effects and continue to evaluate your disease. They will check you every 4 months after you finish your treatment for 2 years, then every 6 months for 3 years, then once every year for your lifetime unless your doctor thinks you need to be seen sooner.

Are there side effects?
There may be some. The chemotherapy and immune therapy drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. Some common side effects of the chemotherapy drugs used in this study include infection, bruising or bleeding, anemia, nausea or vomiting, pain, hair loss, muscle weakness, and more. Some common side effects of nivolumab include anemia, pain, swelling and redness of the eye or injection site, diarrhea, nausea, dry mouth, fever, loss of appetite, and more. 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).