NRG Oncology Clinical Trial: NRG-HN001

Randomized Phase II and Phase III Studies of Individualized Treatment for Nasopharyngeal Carcinoma Based on Biomarker Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA)

About the trial

NRG-HN001 is a clinical trial that is studying how people with nasopharyngeal cancer (in the head and neck region), which has not spread to other parts of the body, respond to different types or levels of chemotherapy, based on a specific DNA viral marker in the blood called the Epstein Barr virus (EBV). Studies have shown an association between the level of EBV DNA found in a patient’s blood and tumor recurrence after chemo-radiation in people with nasopharyngeal cancer. Thus, doctors are investigating whether an individualized treatment plan could be developed using the patient’s EBV DNA as a guide.

If you agree to take part in this study, the EBV DNA level in your blood will be measured before any treatment. If your blood does not have any EBV DNA, you will not be eligible for the study. However, your doctor will discuss other treatment options with you.

There is also an optional Quality of Life study that participants of this trial can partake in. Quality of Life studies allow researchers to learn more about how your cancer treatment affects you. If you choose to participate in this part of the study, you will be asked to fill out forms regarding your physical and emotional well-being, and your general health at various time points before, during, and after treatment.

Evaluating individualized treatment for nasopharyngeal cancer based on the patient’s DNA

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 nasopharyngeal cancer (in the head and neck region) that has not spread to other parts of the body. Your doctor can determine if you meet these 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?
All patients will receive approximately 6 weeks of chemotherapy (cisplatin) and radiation. One week after radiation is completed, your EBV status will be tested and you will be placed into 1 of 4 study groups – Groups 1 and 2 are for those with EBV DNA still in their blood following the 6-week chemo-radiation treatment, and Groups 3 and 4 are for patients with no EBV DNA detected in their blood following the regimen. Groups 1, 2, and 3 will receive varying levels and types of chemotherapy for 12 weeks, and Group 4 will be observed and receive no chemotherapy for 12 weeks. The types of chemotherapy that may be used include cisplatin, 5-fluorouracil, gemcitabine, and paclitaxel.

How long will I be in this study?
You will initially receive approximately 6 weeks of chemotherapy and radiation. Patients assigned to Groups 1, 2, and 3 will receive an additional 12 weeks of chemotherapy. Patients assigned to Group 4 will be observed for 12 weeks and receive no additional chemotherapy. All participants will have follow-up visits every 4 months for 2 years, every 6 months for 3 years, and then once a year for a lifetime.

Are there side effects?
Both radiation therapy and chemotherapy may cause side effects. Your doctor will review all of the potential side effects with you. You are encouraged to tell your doctor about any side effects during the study so that they may be treated and so that potential adjustments to the study drugs may be made.

More Information
Visit the National Cancer Institute website at [https://www.cancer.gov](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) or 1-(800)-4-CANCER (1-800-422-6237)