NRG Oncology Clinical Trial: NRG-GI007

Phase I Trial with Expansion Cohort of OBP-301 (Telomelysin) and Definitive Chemoradiation for Patients with Locally Advanced Esophageal and Gastroesophageal Adenocarcinoma Who are Not Candidates for Surgery

About the trial

The purpose of NRG-GI007 is to find out if it is safe to add OBP-301, known as telomelysin, to the usual treatment of chemotherapy and radiation (chemoradiation) for people with locally advanced esophageal and gastroesophageal cancer who are not candidates for surgery. Telomelysin is a virus that has been designed to infect and destroy only cancer cells (although there is a small risk that it can also infect normal cells). Telomelysin is an experimental drug that is not approved by the U.S. Food and Drug Administration which is why the first step in testing it for people with advanced esophageal cancer is to find out if it is safe to add to the usual treatment of chemoradiation.

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.
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 adenocarcinoma of the esophagus or gastroesophageal junction within 90 days prior to registration, 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?
If you decide to take part in this study, you will get telomelysin injected into your tumor during a procedure called an endoscopy. An endoscopy is a procedure that uses a tiny camera at the end of a long flexible tube to view your esophagus. You had this procedure when you were first diagnosed with cancer. You will receive the telomelysin injections for a total of three times every 14 days. You will receive the first injection before you start chemoradiation and then you will receive the other two injections during the 5 ½ weeks of chemoradiation. After you finish your treatment, your doctor and study team will watch you for side effects.

How long will I be in this study?
After you finish the 5 ½ weeks of chemoradiation and your doctor watches you for side effects, your doctor and study team will check you six to eight weeks after you complete radiation and then every three months for two years after treatment. This means you will keep seeing your doctor for two years after treatment.

Are there side effects?
There are some risks. There is a risk that adding the study agent may not be as good as the usual approach at shrinking or stabilizing your cancer, which is chemoradiation alone. There is also a risk that you could have side effects from the study agent, including fever or chills lasting several days, nausea, fatigue, muscle aches, and more. There is a risk of side effects from the 3 endoscopy procedures required to give the study agent. The most common risks of endoscopy are plain, infection, a tear in the esophagus, bleeding, and a reaction to the sedation given to keep you comfortable during the procedure. These side effects may be worse and may be different than those you would get with the usual approach for your cancer. Some of the most common side effects of the usual chemoradiation that the study doctors know about are: nausea, vomiting, infection, pain, hair loss and tiredness. 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).