NRG Oncology Clinical Trial: NRG-LU004

Phase I Trial of Accelerated or Conventionally Fractionated Radiotherapy Combined With MEDI4736 (durvalumab) in PD-L1 High Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (ARCHON-1)

About the trial

In this clinical trial we are studying if it is safe to add the immunotherapy drug durvalumab to radiation therapy. Durvalumab is FDA approved for treating stage III NSCLC after completing chemotherapy and radiation. It is not FDA approved for use at the same time as radiation, which is what is being studied in this trial.

If you decide to take part in this study, you will receive durvalumab and radiation. You will receive radiation for either three weeks or for six weeks. Each schedule gives the same total dose of radiation. You will receive durvalumab starting two weeks before radiation for up to one year.

To take part in this study you must have non-small cell lung cancer (NSCLC) and your cancer cells express a high level of a protein called PD-L1. Researchers have found that the PD-L1 protein is connected to an improved chance to have a good response to immunotherapy treatment for cancer.

After you finish the study treatment, your doctor will continue to follow your condition for another year (for a total of two years of participation in this study) and watch you for side effects. After this time, your treating physician will discuss usual care options and follow up for your cancer.

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 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 locally advanced NSCLC whose cancer cells express a high degree of the protein PD-L1. Your doctor can determine if you meet these requirements.

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?
Everyone taking part in this study will get the same dose of durvalumab and the same total dose of radiation. Participants will start durvalumab two weeks before radiation and take it for up to one year. Some people in the study will get the total dose of radiation over 3 weeks and some people will receive the total dose of radiation over 6 weeks.

How long will I be in this study?
The study treatment period may last up to one year and participants will be followed for an additional year for a total of two years in the study. After you finish study treatment, your doctor will continue to follow your condition for one year and watch you for side effects. After this time, your treating physician will discuss usual care options and continue to follow you.

Are there side effects?
There may be. Some of the most common side effects of radiation that the study doctors know about are lung inflammation and scarring, esophageal irritation, and fatigue. Some of the most common side effects of durvalumab that the study doctors know about are itching and rash. There may be some side effects of durvalumab 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)