NRG Oncology Clinical Trial RTOG 1308
RTOG 1308, Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Therapy Chemoradiotherapy for Inoperable Stage II-IIIB NSCLC

About the trial
Radiotherapy is typically used to treat lung cancer when surgery is not an option. Chemotherapy is usually given during and after radiotherapy. There are two types of radiation treatments used for radiotherapy. Photon therapy uses high-energy x-rays to send the radiation inside the body to the tumor. The second type of radiotherapy treatment is called proton therapy, which uses a beam of proton particles to send radiation inside the body to the tumor. Both types of radiotherapy use special images to help guide accurate delivery of a full dose of radiation to the tumor without damaging much of the healthy tissue around it.

This study will combine a chemotherapy regimen approved by the FDA with each radiotherapy type for your lung cancer so that NRG Oncology can compare the impact these treatments have on patient life span and side effects.

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Comparing Photon Therapy to Proton Therapy to Treat Patients with Lung Cancer

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research of the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Radiation Therapy Oncology Group (RTOG), and the Gynecologic Oncology Group (GOG). The research network seeks to carry out clinical trials with emphases 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 located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI’s National Clinical Trials Network.
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?
In addition to having non-small cell lung cancer (NSCLC) that is unable to be operated on, there are other eligibility requirements to participate in this study. 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?
This study has two study groups. Group 1 will receive a typical chemotherapy used for this type of lung cancer (to be decided by you and your study doctor) along with the usual radiotherapy used for this type of lung cancer (photon radiotherapy). You will receive chemotherapy through a vein either once a week during radiotherapy or during the first and fifth weeks of radiotherapy. Group 2 will get the usual chemotherapy used for this type of lung cancer, as described above, along with radiotherapy that is experimental in this type of lung cancer (proton radiotherapy). After chemoradiation, you may either receive additional doses of the same chemotherapy or you may receive the immune therapy drug, durvalumab.

How long will I be in this study?
You will receive chemotherapy and radiotherapy for about 6 to 7 weeks. You may then receive immune therapy every month for up to 12 months, or you may receive an additional one or two doses of chemotherapy every 21 days depending on the type of chemotherapy you received during radiation. After you finish the study treatment, your doctor will continue to watch you for side effects and follow your condition.

Are there side effects?
Possible risks of chemotherapy include nausea, vomiting, diarrhea, hair loss, anemia, infection, bruising and bleeding, sores in your mouth, tiredness. Possible risks of durvalumab include rash or itching, diarrhea, nausea, vomiting, fatigue, fever, loss of appetite, shortness of breath; durvalumab may also cause your immune system to attack normal organs and cause side effects in many parts of the body. Possible risks for patients receiving lung radiotherapy include swelling, redness, thickening, tanning, numbness, or peeling of the skin in the area of radiation, difficulty swallowing, hair loss in the treatment area, shortness of breath or cough, tiredness, diarrhea, nausea, anemia, infection, bleeding, bruising, and rib pain. Your doctor will review all of the potential side effects with you.

More Information
You may visit the NCI website at cancer.gov for more information about studies or general information about cancer.

You may also call the NCI Cancer Information Service to get the same information at 1-(800)-4-CANCER (1-800-422-6237)