ACTIVE, NOT RECRUITING

Comparing Photon Therapy To Proton Therapy To Treat Patients With Lung Cancer

ClinicalTrials.gov ID NCT01993810

Sponsor Radiation Therapy Oncology Group

Information provided by Radiation Therapy Oncology Group (Responsible Party)

Last Update Posted 2023-10-06

Study Details Tab

Study Overview

Brief Summary

This randomized phase III trial studies proton chemoradiotherapy to see how well it works compared to photon chemoradiotherapy in treating patients with stage II-IIIB non-small cell lung cancer that cannot be removed by surgery. Specialized radiation therapy that delivers a high dose of radiation directly to the tumor, such as photon or proton beam radiation therapy, may kill more tumor cells and cause less damage to normal tissue. Drugs used in chemotherapy, such as paclitaxel, carboplatin, etoposide, and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. It is not yet known whether proton chemoradiotherapy is more effective than photon chemoradiotherapy in treating non-small cell lung cancer.

Detailed Description

PRIMARY OBJECTIVES:

I. To compare the overall survival (OS) in patients with stage II-IIIB non-small cell lung cancer (NSCLC) after image guided, motion-managed photon radiotherapy (Arm 1) or after image guided, motion-managed proton radiotherapy (Arm 2) both given with concurrent platinum- based chemotherapy.

II. To compare the cardiac toxicity and lymphocyte reduction (lymphopenia) definitely, probably, or possibly related to treatment between the 2 arms.

SECONDARY OBJECTIVES:

I. To compare 2-year progression-free survival (PFS) between the 2 arms. II. To compare the development of grade 3 or higher adverse events not included above that are definitely, probably, or possibly related to treatment.

III. To compare differences between the two arms in quality of life (QOL) based primarily on the development of shortness of breath at 6 months and secondarily on the development of sore throat at the end of chemoradiotherapy (chemoRT) (as measured by the lung cancer module of the MD Anderson Symptom Inventory [MDASI-Lung]), as well as breathing related functioning impairments as measured by the Shortness Breath Questionnaire [SOBQ].

IV. To compare cost-effectiveness outcomes between the 2 arms. V. To compare pulmonary function changes by treatment arms and response. VI. To explore the most appropriate and clinically relevant technological parameters to ensure quality and effectiveness throughout radiation therapy processes, including imaging, simulation, patient immobilization, target and critical structure definition, treatment planning, image guidance and delivery.

OUTLINE: Patients are randomized to 1 of 2 treatment arms.

ARM I: Patients undergo photon beam radiation therapy 5 days per week for a total of 35 fractions and receive either paclitaxel* intravenously (IV) over 1 hour and carboplatin* IV weekly during radiation therapy or etoposide IV on days 1-5 and 29-33 and cisplatin IV on days 1, 8, 29, and 36. Patients with non-squamous cell cancera may receive pemetrexed IV and carboplatin IV on every 21 days.

ARM II: Patients undergo proton beam radiation therapy 5 days per week for a total of 35 fractions and receive either paclitaxel* and carboplatin*, etoposide and cisplatin, or pemetrexed and carboplatin (for non-squamous cell cancer patients only) as in Arm I.

*In both arms, patients who receive paclitaxel and carboplatin must complete 2 courses of consolidation therapy.

CONSOLIDATION THERAPY: Beginning 3-6 weeks after chemoradiotherapy, patients receive either paclitaxel IV over 3 hours and carboplatin IV on day 1 or durvalumab IV every 2 weeks. Treatment repeats every 21 days for 2 courses or every 2 weeks for up to 12 months for durvalumab in the absence of disease progression or unacceptable toxicity. Patients with non-squamous cell carcinoma may receive durvalumab or pemetrexed IV and carboplatin IV on day 1 every 21 days for up to 4 courses.

After completion of study treatment, patients are followed up at 4-8 weeks, every 3 months for 1 year, every 6 months for 1 year, and then annually thereafter.

Official Title

Phase III Randomized Trial Comparing Overall Survival After Photon Versus Proton Chemoradiotherapy for Inoperable Stage II-IIIB NSCLC

Conditions

Stage II Non-Small Cell Lung Cancer AJCC v7

Stage IIA Non-Small Cell Lung Carcinoma AJCC v7

Stage IIB Non-Small Cell Lung Carcinoma AJCC v7

Stage III Non-Small Cell Lung Cancer AJCC v7

Intervention / Treatment

- Drug: Carboplatin
- Drug: Cisplatin
- Biological: Durvalumab
- Drug: Etoposide

Other Study ID Numbers

- **RTOG 1308**
- NCI-2013-01850 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))

Study Start (Actual)

2014-02-03

Primary Completion (Estimated)

2024-12-01

Study Completion (Estimated)

2025-10

Enrollment (Actual)

330

Study Type

Interventional

Phase

Phase 3

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Lung cancer (https://medlineplus.gov/genetics/condition/lung-cancer)

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

United States

Florida Locations

Jacksonville, Florida, United States, 32209
University of Florida Health Science Center - Jacksonville

Illinois Locations

Warrenville, Illinois, United States, 60555
Northwestern Medicine Cancer Center Warrenville

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- Histologically or cytologically proven diagnosis of non-small cell lung cancer
- Clinical American Joint Committee on Cancer (AJCC) (AJCC, 7th ed.) II, IIIA or IIIB (with non-operable disease; non-operable disease will be determined by a multi-disciplinary treatment team within 60 days prior to registration; note: for patients who are clearly nonresectable, the case can be determined by the treating radiation oncologist and/or a medical oncologist or pulmonologist
    - Patients who present with N2 or N3 disease and an undetectable NSCLC primary tumor are eligible
    - Patients who refuse surgery are eligible
    - Patients who develop local recurrence after surgery and rendered candidate for definitive concurrent chemoradiation are also eligible
    - Patients who have received systemic treatment (up to 4 cycles of induction chemotherapy, or up to 6 months of targeted therapy) are eligible
- Appropriate stage for protocol entry, including no distant metastases, based upon the following minimum diagnostic workup:
    - History/physical examination within 30 days prior to registration including resting heart rate;
    - Fludeoxyglucose F 18 (FDG)-positron emission tomography (PET)/computed tomography (CT) scan for staging within 60 days prior to registration
    - Magnetic resonance imaging (MRI) scan with contrast of the brain (preferred) or CT scan of the brain with contrast within 60 days prior to registration;
    - Forced expiratory volume in one second (FEV1) >= 0.8 liter or >= 35% predicted with or without bronchodilator within 90 days prior to registration;
        - Patients who meet the criterion above without oxygen (O2), but who need acute (started within 10 days prior to registration) supplemental oxygen due to tumor-caused obstruction/hypoxia are eligible, provided the amount of the O2 needed has been stable
- Zubrod performance status 0-1 within 30 days prior to registration
- Absolute neutrophil count (ANC) >= 1,500 cells/mm^3 obtained within 30 days prior to registration
- Platelets >= 100,000 cells/mm^3 obtained within 30 days prior to registration
- Hemoglobin >= 9.0 g/dl (note: the use of transfusion or other intervention to achieve hemoglobin [Hgb] >= 9.0 g/dl is acceptable), obtained within 30 days prior to registration
- Serum glutamic oxaloacetic transaminase (SGOT) or serum glutamate pyruvate transaminase (SGPT) within 30 days prior to registration
    - It is highly recommended but not required that SGOT or SGPT be =< 1.5 upper limit of normal
- Total bilirubin =< 1.5 within 30 days prior to registration

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- Serum creatinine < 1.5 mg/dL or calculated creatinine clearance >= 50 mL/min within 30 days prior to registration estimated by the Cockcroft-Gault formula
- Peripheral neuropathy =< grade 1 at the time of registration
- Patients with non-malignant pleural effusion are eligible
    - If a pleural effusion is present, the following criteria must be met to exclude malignant involvement:
        - When pleural fluid is visible on both the CT scan and on a chest x-ray, a pleuracentesis is required to confirm that the pleural fluid is cytologically negative
        - Exudative pleural effusions are excluded, regardless of cytology
        - Effusions that are minimal (i.e, not visible on chest x-ray) that are too small to safely tap are eligible
- Patients must have measurable or evaluable disease
- Women of childbearing potential must have a negative serum pregnancy test within 14 days prior to registration
- Women of childbearing potential and male participants must practice adequate contraception
- Patient must provide study-specific informed consent prior to study entry

Exclusion Criteria:

- Prior invasive malignancy unless disease free for a minimum of 3 years; however, skin cancer and in situ carcinomas of the breast, oral cavity, cervix, and other organs and are permissible
- Patients with prior history of either small cell lung cancer or NSCLC regardless of the treatment received, other than patients who have recurrent disease following resection
- Prior systemic chemotherapy for the study cancer, if more than 4 cycles of induction chemotherapy or more than 6 months of targeted therapy; note that prior chemotherapy for a different cancer is allowable
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields
- Severe, active co-morbidity, defined as follows:
    - Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months;
    - Transmural myocardial infarction within the last 6 months;
    - Chronic obstructive pulmonary disease exacerbation or other respiratory illness other than the diagnosed lung cancer requiring hospitalization or precluding study therapy within 30 days before registration;
    - Acquired immune deficiency syndrome (AIDS) based upon current Centers for Disease Control and Prevention (CDC) definition; note, however, that human immunodeficiency virus (HIV) testing is not required for entry into this protocol
- Unintentional weight loss > 10% within 30 days prior to registration

- Pregnancy or women of childbearing potential and men who are sexually active and not willing/able to use medically acceptable forms of contraception

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Overall Survival	The time from study registration until death or last follow-up	From registration until death or last follow-up; analysis occurs after 390 deaths

		have been reported

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Progression-free survival	The time from study registration until the first occurrence of local, regional, or distant progression, or death from any cause, or until last follow-up	From registration to date of local failure, regional failure, distant failure, death from any cause, or until last follow-up. Analysis occurs after 390 deaths have been reported.
Adverse events	Incidence of treatment-related grade 3-5 adverse events, graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.0	From start of treatment to end of follow-up

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Radiation Therapy Oncology Group

Collaborators

- National Cancer Institute (NCI)
- NRG Oncology

Investigators

- Principal Investigator: Zhongxing Liao, NRG Oncology

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2013-11-12

First Submitted that Met QC Criteria

2013-11-20

First Posted (Estimated)

2013-11-25

Study Record Updates

Last Update Submitted that met QC Criteria

2023-10-03

Last Update Posted

2023-10-06

Last Verified

2023-10

More Information

Terms related to this study

Additional Relevant MeSH Terms

Neoplasms, Glandular and Epithelial
Neoplasms by Histologic Type
Neoplasms
Respiratory Tract Neoplasms
Thoracic Neoplasms
Neoplasms by Site
Lung Diseases
Respiratory Tract Diseases
Carcinoma, Bronchogenic
Bronchial Neoplasms
Carcinoma
Lung Neoplasms
Carcinoma, Non-Small-Cell Lung
Antineoplastic Agents, Phytogenic
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Topoisomerase II Inhibitors
Topoisomerase Inhibitors
Enzyme Inhibitors
Folic Acid Antagonists
Nucleic Acid Synthesis Inhibitors
Antineoplastic Agents, Immunological

Immunologic Factors
Physiological Effects of Drugs
Keratolytic Agents
Dermatologic Agents
Paclitaxel
Etoposide
Podophyllotoxin
Cisplatin
Carboplatin
Pemetrexed
Albumin-Bound Paclitaxel
Etoposide phosphate
Durvalumab
Immunoglobulins
Antibodies, Monoclonal
Immunoglobulin G

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No