# CALGB-30610

# Phase III Comparison of Thoracic Radiotherapy Regimens in Patients With Limited Small Cell Lung Cancer Also Receiving Cisplatin and Etoposide

**ClinicalTrials.gov Identifier: NCT00632853**

## Study Background

### Trial Description

Radiation therapy uses high-energy x-rays to kill tumor cells. Drugs used in chemotherapy, such as etoposide, carboplatin and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known which radiation therapy regimen is more effective when given together with chemotherapy in treating patients with limited-stage small cell lung cancer. This randomized phase III trial is comparing different chest radiation therapy regimens to see how well they work in treating patients with limited-stage small cell lung cancer.

### Arms:

Arm A - Standard Radiotherapy + Chemotherapy: (Active Comparator): Radiotherapy (every day, Monday-Friday, for a total of 3 weeks) XRT: 45 Gy BID (1.5 Gy/fx) starting on day 1 of Cycle 1 or 2, every day, for 3 weeks Chemotherapy (every 21 days for 4 cycles, for a total of 12 weeks): Cisplatin 80 mg/m2 IV on day 1 OR Carboplatin AUC 5 IV day 1, every 21 days Etoposide 100 mg/m2 IV Register/ on days 1, 2, and 3, every 21 days

Arm B - High Dose Radiotherapy + Chemotherapy: (Experimental): Radiotherapy (every day, Monday-Friday, for a total of 7 weeks) XRT: 70 Gy QD (2.0 Gy/fx), starting on day 1 of Cycle 1 or 2, every day, for 7 weeks Chemotherapy (every 21 days for 4 cycles, for a total of 12 weeks): Cisplatin 80 mg/m2 IV on day 1 OR Carboplatin AUC 5 IV day 1, every 21 days Etoposide 100 mg/m2 IV on days 1, 2, and 3, every 21 days

### Objectives:

OUTLINE: This is a 2-part, multicenter, randomized study. Patients are stratified according to gender, weight loss 6 months prior to study entry (≤5% of body weight vs > 5% of body weight), ECOG performance status (0 vs 1 vs 2), radiotherapy technique (intensity-modulated radiotherapy vs 3-dimensional conformal radiotherapy), radiotherapy start time (at first cycle of protocol chemotherapy, after one cycle of prior non-protocol chemotherapy vs at first cycle

of protocol chemotherapy, without prior non-protocol chemotherapy vs at second cycle of protocol chemotherapy, without prior non-protocol chemotherapy) and chemotherapy backbone: carboplatin vs cisplatin.

OBJECTIVES:

Primary Objective: To determine whether administering high dose thoracic radiotherapy, 70 Gy (2 Gy once-daily over 7 weeks) or 61.2 Gy (1.8 Gy once-daily for 16 days followed by 1.8 Gy twice-daily for 9 days), will improve median and 2-year survival compared with 45 Gy (1.5 Gy twice-daily over 3 weeks) in patients with limited stage small cell lung cancer.

Secondary Objectives

1. To compare treatment related toxic effects of thoracic radiotherapy regimens in patients with limited stage small cell lung cancer
2. To compare response rates, failure-free survival and toxicity of thoracic radiotherapy regimens in patients with limited stage small cell lung cancer
3. To compare rates of local relapse, distant metastases and brain metastases with these regimens
4. To compare patients' quality of life between these treatment regimens in terms of their physical symptoms, physical functioning and psychological state
5. To describe the patterns of use of thoracic intensity modulated radiation therapy (IMRT) in patients with limited stage small cell lung cancer
6. To examine blood-based biomarkers of response and resistance to cisplatin (or carboplatin) and etoposide
7. To evaluate the correspondence between increases in plasma ProGRP concentrations and disease progression/recurrence
8. To evaluate the potential for plasma ProGRP concentrations at baseline, after each cycle of chemotherapy and at first evaluation following completion of chemotherapy to predict PFS and OS
9. To evaluate the correspondence between longitudinal decreases in plasma ProGRP concentrations and clinical response

Part 1: Patients are randomized to 1 of 3 treatment arms.

Arm I: Patients undergo standard-dose (45 Gy given in 30 treatments) thoracic radiotherapy twice daily, 5 days a week, for 3 weeks. Patients also receive cisplatin IV on day 1 or carboplatin IV and etoposide IV on days 1, 2, and 3.

Arm II: Patients undergo higher-dose (70 Gy given in 35 treatments) thoracic radiotherapy once daily, 5 days a week, for 7 weeks. Patients also receive cisplatin or carboplatin and etoposide as in arm I.

Arm III: (discontinued as of 03/10/13) Patients undergo mid-dose (61.2 Gy given in 34 treatments) thoracic radiotherapy once daily, 5 days a week, during the initial 16 days (approximately 3 weeks) of treatment and then twice daily, 5 days a week, for the final 9 days (approximately 2 weeks) of treatment. Patients also receive cisplatin and etoposide.

In all arms, treatment with cisplatin and etoposide repeats every 21 days for 4 courses in the absence of disease progression or unacceptable toxicity.

Part 2: An interim analysis was conducted after accrual of 30 patients per arm and one experimental arm based upon a comparison of treatment-related toxicity was selected. The most toxic experimental arm was discontinued, and the trial continues comparing standard therapy (arm I) to the selected experimental regimen (arm II) as described in part 1. Please see the Arms section for more information regarding Part 2.
Prophylactic cranial irradiotherapy (PCI): Within 3-6 weeks after completion of chemotherapy, PCI should be offered to all patients with a complete tumor response (CR) or near complete response (nCR) with only residual chest abnormalities of indeterminate nature following completion of combined modality therapy.
After completion of study treatment, patients are followed up at least every 3 months for 2 years, every 6 months for 3 years, and then annually for 5 years or until disease progression. At disease progression, patients are followed up every 6 months.

## Study Milestones:

Start date: March 2008

Primary Completion Date: March 2, 2022

## Publication Information:

Analysis Type: Primary

PubMed ID: 36623230

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Associated Datasets: NCT00632853-D1-Dataset.csv (patients), NCT00632853-D2-Dataset.csv (ae), NCT00632853-D3-Dataset.csv (arm3)

## Dataset Information:

Dataset Name: NCT00632853-D3-Dataset.csv (arm3)

Description: Dataset NCT00632853-D3-Dataset.csv (arm3) is one of 3 datasets associated with PubMed ID 36623230. This dataset contains patients for arm 3 represented in the consort diagram.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

## NCT00632853-D3-Dataset.csv (arm3) Data Dictionary:

| LABEL | NAME | ELEMENTS | COMMENTS |
|---|---|---|---|
| Patient ID | patid | | |
| Treatment Arm | arm | Assigned to 61.2 Gy CB | |