CALGB (Alliance) 30610: Phase III Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide

Jeffrey Bogart, MD

State University of New York Upstate Medical University

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Rationale

Traditionally, small cell lung cancer was treated with modest total doses of fractionated thoracic radiation (TRT), 45–50 Gy, but durable local tumor control is poor with intrathoracic tumor failure in more than 50% of patients treated with 45 Gy once-daily (QD) radiotherapy concurrent with cisplatin and etoposide on Intergroup trial 0096 (INT 0096).Intensifying the radiotherapy course by accelerating the time to complete treatment appears to be effective with improved overall survival for patients assigned to 150 cGy twice daily x 30 fractions on INT 0096 . Despite this result, the 45 Gy BID TRT regimen has not been well accepted in clinical practice, and high dose (60 Gy +) QD TRT is frequently used in practice without sufficient level 1 evidence. The results of CALGB 30610, comparing 45 y BID with 70 Gy QD TRT, will help define the therapeutic index of each approach and add to data from the recently published CONVERT trial which studied 66 Gy QD TRT.

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Objective

Primary

- To determine whether administering high dose thoracic radiotherapy, 70 Gy (2 Gy once-daily over 7 weeks) 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

- To compare treatment related toxic effects of thoracic radiotherapy regimens in patients with limited stage small cell lung cancer.
- To compare response rates, failure-free survival and toxicity of thoracic radiotherapy regimens in patients with limited stage small cell lung cancer.
- To compare rates of local relapse, distant metastases and brain metastases with these regimens.

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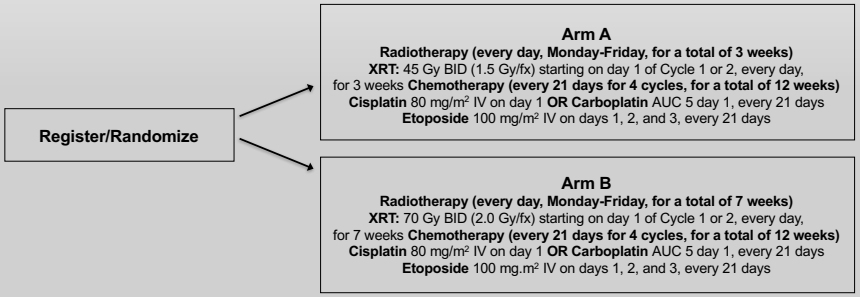
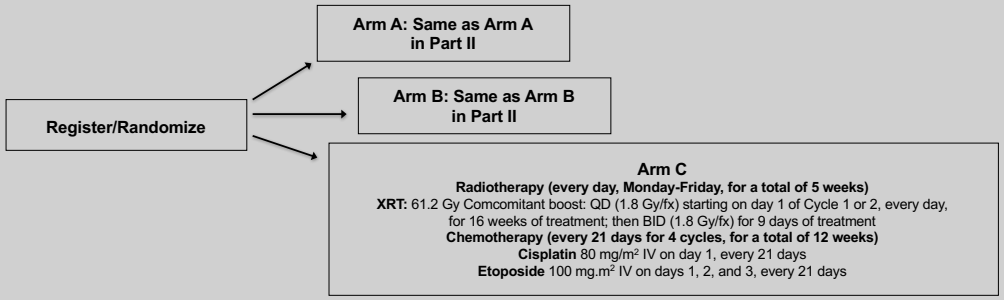
Study Schema

(1 cycle = 21 days)
Patients will receive 4 cycles of chemotherapy
Part II: Based on the results of Part I, the experimental arm (Arm C) was discontinued and patients are randomized (as of 03/11/2013) as follows:



Prophylactic cranial irradiation (PCI) should be offered to all patients with a complete or near CR.

PART I CLOSED TO FURTHER ACCRUAL EFFECTIVE MARCH 30, 2013



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Treatment Plan

- Patients registered to CALGB 30610 prior to the start of cycle 1 protocol treatment will start therapy within 7 days of registration.
- Questions regarding treatment should be directed to the Alliance Study Chair.
- Protocol therapy will consist of 4 cycles of cisplatin and etoposide or carboplatin and etoposide chemotherapy administered every 21 days. Thoracic radiotherapy will begin either on the first day of the first cycle of chemotherapy OR on the first day of the second cycle of chemotherapy.
- Patients may be registered to CALGB 30610 following one cycle of chemotherapy. Patients must receive the second cycle of therapy following registration, on day 22-24, so that the patient adheres to a 3-week treatment cycle. Patients not able to be treated within 3 days of day 22 should not be registered to CALGB 30610. For patients registered to CALGB 30610 after 1 cycle of chemotherapy, the thoracic radiotherapy must begin with the second cycle of chemotherapy (the first cycle of protocol chemotherapy after the patient was registered). Additionally, the cycle of chemotherapy given prior to registration will be considered “cycle 1.” Therefore, patients registered following 1 cycle of chemotherapy will receive three cycles of therapy after registration.
- The original design was a randomized phase III trial including two experimental treatment arms (70 Gy once daily radiotherapy and 61.2 Gy concomitant boost radiotherapy) and a standard treatment arm (45 Gy twice daily radiotherapy). An interim analysis, conducted after accrual of a pre-determined number of patients, selected one experimental arm based upon a comparison of treatment related toxicity. Arm C was discontinued, and the trial now compares standard therapy to the selected experimental regimen.

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Eligibility Criteria

- Histologically or cytologically documented small cell lung cancer of limited stage.
- Measurable disease.
- No prior chemotherapy or radiotherapy for SCLC, apart from 1 cycle of chemotherapy
- No prior mediastinal or thoracic radiotherapy.
- Patients with complete surgical resection of disease are not eligible.
- Age ≥ 18 years.
- ECOG Performance Status 0-2.
- Non-pregnant and non-nursing.
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Funding Support

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