C30610 – RTOG 0538

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

Active Comparator: Arm I	Experimental: Arm II
Patients undergo standard-dose (45 Gy given) thoracic radiotherapy twice daily, every day, for 3 weeks. Cisplatin 80mg/m2 OR Carboplatin AUC 5 IV D1 every 21 days Etoposide 100mg/m2 D 1, 2, 3 every 21 days for 4 cycles for a total of 12 weeks.	Patients undergo higher-dose (70 Gy) thoracic radiotherapy once daily, every day, for 7 weeks. Cisplatin 80mg/m2 OR Carboplatin AUC 5 IV D1 every 21 days Etoposide 100mg/m2 D 1, 2, 3 every 21 days for 4 cycles for a total of 12 weeks.

DISEASE CHARACTERISTICS:

- Histologically or cytologically documented small cell lung cancer (SCLC)
  - Limited-stage disease
    - Disease restricted to one hemithorax with regional lymph node metastases, including ipsilateral hilar, ipsilateral and contralateral mediastinal, and ipsilateral supraclavicular lymph nodes
- The following patients are <u>not</u> eligible:
  - Patients with disease involvement of the contralateral hilar or supraclavicular lymph nodes
  - Patients with pleural effusions that are visible on plain chest radiographs, whether cytologically positive or not
  - Patients with cytologically positive pleural or pericardial fluid, regardless of the appearance on plain x-ray
- Measurable disease, defined as at least one unidimensionally measurable lesion ≥ 2 cm by conventional techniques OR ≥ 1 cm by spiral CT scan

PATIENT CHARACTERISTICS:

- ECOG PS 0-2
- Granulocytes ≥ 1,500/µl
- Platelet count ≥ 100,000/µl
- Total bilirubin ≤ 1.5 times upper limit of normal (ULN)
- AST ≤ 2.0 times ULN
- Serum creatinine ≤ 1.5 times ULN OR creatinine clearance ≥ 70 mL/min
- Not pregnant or nursing

PRIOR CONCURRENT THERAPY:

- Patients may have received one and only one course of chemotherapy prior to enrolling on CALGB 30610, which must have included cisplatin and etoposide
  - If a patient has had one course of cisplatin/etoposide prior to registration, the patient must have had all of the prior-to-registration tests prior to starting their first course of chemotherapy
  - Registration to CALGB-30610 must take place within 14-21 days after the start of the non-protocol therapy; failing to do all of the above will make the patient NOT eligible for CALGB-30610
    - No prior radiotherapy or chemotherapy (except for the chemotherapy described above) for SCLC
    - No prior mediastinal or thoracic radiotherapy
    - No prior complete surgical resection of SCLC