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ABSTRACT

A COMPARISON OF "BEST LOCAL-REGIONAL THERAPY" WITH OR WITHOUT CHEMOTHERAPY FOR STAGE IIIA (N2) NON-SMALL CELL LUNG CANCER: A RANDOMIZED PHASE III STUDY: CALGB 9134

This study will test the value of adding adjuvant chemotherapy to best local-regional therapy in patients with resectable stage III non-small cell lung cancer, i.e, patients with T1-3, N2 tumors. These patients are currently approached in various ways at different institutions utilizing different combinations of radiotherapy, surgery and chemotherapy. Primary radiotherapy is the most commonly used approach and is associated with a cure rate of less than 10%. Surgery plus radiotherapy is considered the best local-regional therapy currently available. Patients in this study will be randomized to receive either chemotherapy with cisplatin/etoposide and G-CSF plus surgery/radiotherapy, or surgery radiotherapy alone. In the chemotherapy arm, patients will get 2 cycles of chemotherapy followed by surgery followed by 2 additional cycles of chemotherapy followed by radiotherapy. In the control arm patients will get 40Gy pre-op radiotherapy followed by surgery followed by an additional 16-20Gy radiotherapy. It is planned to enroll approximately 125 patients per arm.

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ENCLOSURE (4)