

A Study that Compares Overall Survival in High Risk Patients with Stage I Non-Small Cell Lung Cancer Receiving Either Lung Surgery Followed by Brachytherapy or Lung Surgery Alone

INCLUSION CRITERIA:

Pre-Operative Criteria (Pre-registration):

1. Patients must have suspicious lung nodule for clinical stage I NSCLC.
2. Patients must have a mass less than or equal to 3 cm maximum diameter by CT size estimate: clinical stage Ia or selected Ib (i.e., with visceral pleural involvement).
3. Patient must have a CT scan of the chest with upper abdomen within 60 days of prior to pre-registration.
4. Patient must have an ECOG/Zubrod performance status 0, 1, or 2.
5. Patient must meet at least one major criteria or meet a minimum of two minor criteria as described below:
Major Criteria
> FEV1% less than or equal to 50%
> DLCO less than or equal to 50%
Minor Criteria
> Age greater than or equal 75 years old
> FEV1 51-60% predicted
> DLCO 51-60% predicted
> Pulmonary Hypertension (pulmonary artery systolic pressure greater than 40mmHg) as estimated by echocardiography or right heart catheterization
> Poor left ventricular function (defined as an ejection fraction of 40% or less)
> Resting or Exercise Arterial pO₂ less than or equal to 55mm Hg or SpO₂ less than or equal to 88%
> pCO₂ > 45 mm Hg
> Modified Medical Research Council (MMRC) Dyspnea Scale greater than or equal to 3.
6. Patient must not have had previous intra-thoracic radiation therapy.
7. Women of child-bearing potential must have negative serum or urine pregnancy test.
8. Patient, or patient's legally acceptable representative, must provide a signed and dated written informed consent PRIOR to registration and any study-related procedures being performed.
9. Patient or the patient's legally acceptable representative must provide written authorization to allow the use and disclosure of their protected health information.

Intra-Operative Criteria (Randomization/Registration):

1. Patient must have biopsy-proven NSCLC.
2. Patient must have all suspicious mediastinal lymph nodes (>1 cm on CT scan or positive on PET scan) assessed by one of the following methods to confirm negative involvement with NSCLC (Mediastinoscopy, endo-esophageal ultrasound guided needle aspiration, CT-guided, video-assisted thoracoscopic or open lymph node biopsy).

EXCLUSION CRITERIA:

1. Pregnant women.