Stablemates Trial

A randomized phase III study of sublobar resection (SR) versus stereotactic ablative radiotherapy (SAbR) in high risk patients with stage I non-small cell lung cancer (NSCLC)

Eligibility summary (*see full criteria in protocol*)

- Age > 18 years.
- ECOG performance status 0, 1, or 2.
- Radiographic findings consistent with NSCLC, including lesions with ground glass opacities with a solid component of 50% or greater.
- Biopsy confirmed NSCLC.
- Tumor ≤ 4 cm maximum diameter, including clinical stage IA and selected IB by PET/CT scan of the chest and upper abdomen performed within 90 days prior to registration.
- All clinically suspicious mediastinal N1, N2, or N3 lymph nodes (> 1 cm short-axis dimension on CT scan and/or positive on PET scan) confirmed negative for involvement with NSCLC by one of the following methods: mediastinoscopy, anterior mediastinotomy, EUS/EBUS guided needle aspiration, CT-guided, video-assisted thoracoscopic or open lymph node biopsy.
- Tumor verified by a thoracic surgeon to be in a location that will permit sublobar resection.
- Tumor located peripherally within the lung. NOTE: Peripheral is defined as not touching any surface within 2 cm of the proximal bronchial tree in all directions. Patients with non-peripheral (central) tumors are NOT eligible.
- No evidence of distant metastases.
- Availability of pulmonary function tests (PFTs – spirometry, DLCO, +/- arterial blood gases) within 90 days prior to registration. Patients with tracheotomy, etc, who are physically unable to perform PFTs (and therefore cannot be tested for the Major criteria below) are potentially still eligible if a study-credentialed thoracic surgeon documents that the patient's health characteristics would otherwise have been acceptable for eligibility as a high risk but nonetheless operable patient.
- Patient at high risk for surgery by meeting a minimum of one major criteria or two minor criteria as described below:

Major Criteria

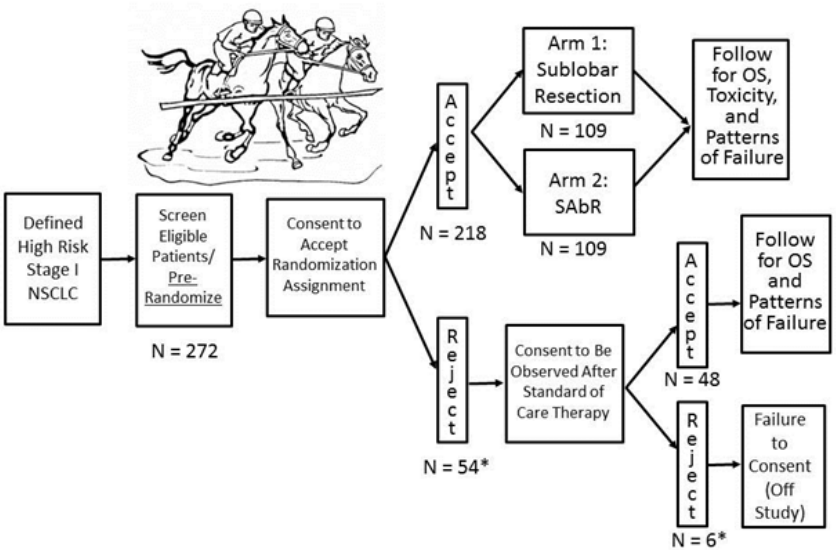
- FEV1 ≤ 50% predicted
- DLCO ≤ 50% predicted

Minor Criteria

- Age ≥75
- FEV1 51-60% predicted
- DLCO 51-60% predicted
- Pulmonary hypertension (pulmonary artery systolic pressure greater than 40mm Hg) as estimated by echocardiography or right heart catheterization
- Poor left ventricular function (ejection fraction of 40% or less)
- Resting or exercise arterial pO2 ≤ 55 mm Hg or SpO2 ≤ 88%
- pCO2 > 45 mm Hg
- Study-credentialed thoracic surgeon believes patient is potentially operable but that a lobectomy or pneumonectomy would be poorly tolerated for tangible or intangible reasons.
- MMRC Dyspnea Scale ≥ 3

- No prior intrathoracic radiation therapy. Previous chemotherapy or surgical resection specifically for the lung cancer being treated on this protocol is NOT permitted. No prior lung resection on the ipsilateral side.
- Disease-free for ≥ 3 years of any prior invasive malignancies (exceptions: non-melanoma skin cancer, in-situ cancers).

Trial schema



Patient talking points

- Standard therapy for early-stage lung cancer is lobectomy (removal of a lobe) for average-risk patients.
- Standard therapy for high-risk operable patients with stage I lung cancer who can still tolerate anesthesia is sublobar resection (removal of less than a lobe).
- You are considered high-risk for lobectomy and ordinarily would be offered sublobar resection as standard of care treatment.
- In this study, you could receive SAbR, a new treatment that uses highly focused radiation therapy to destroy lung cancers.
- The results of SAbR for medically inoperable patients have been much better than traditional radiotherapy and may approach the results of sublobar resection.
- If you choose to participate you will be offered one of these treatments as pre-assigned by computer. If you choose the other treatment you may still participate by allowing us to collect information about your treatment.