Protocol Title: JoLT-Ca 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) (STABLE-MATES Trial)

Target Population: Non-Small Cell Lung Cancer (NSCLC)

Summary: Stereotactic Ablative Radiotherapy has been shown in single institution Phase II and matched cohort studies to be effective at controlling primary early Lung Cancer. Recent pooled analysis of both the STARS and ROSEL randomized trials comparing SABR versus Lobectomy have shown a significantly improved 3-Year survival with SABR, giving further impetus for successful completion of a randomized trial.

Key Inclusion Criteria:
- Radiographic findings consistent with Non-Small Cell Lung Cancer, including lesions with ground glass opacities with a solid component of 50% or greater.
  - Those with ground glass opacities and < 50% solid component will be excluded.
- Biopsy confirmed Non-Small Cell Lung Cancer.
- Tumor ≤ 4 cm maximum diameter, including clinical Stage IA and selected IB by PET / CT Scan of the Chest and Upper Abdomen performed within 60 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 1 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 (e.g., Spirometry, DLCO, +/- Arterial Blood Gases) within 90 Days prior to registration.
  - Patients with tracheotomy, etc., who are physically unable to perform Pulmonary Function Tests 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 (in particular be eligible for Sublobar Resection).
- No prior intra-thoracic radiation therapy.

Key Exclusion Criteria:
- Evidence of distant metastases.
- Prior intra-thoracic radiation therapy.
  - NOTE: Previous radiotherapy as part of treatment for Head and Neck, Breast, or other Non-Thoracic Cancer is permitted so long as possible radiation fields would not overlap.
  - 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.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02468024

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