

A Study Available for Stage I Non-Small Cell Lung Cancer (NSLC)

A Phase III International Randomized Study to Compare CyberKnife (CK) SBRT (Stereotactic Radiotherapy) with Surgery

Objective:

- To compare overall survival
- To compare time to local recurrence, time to regional recurrence, time to disseminated recurrence, and progression-free survival
- To compare grade 3 and above acute and/or chronic toxicities

Eligibility Criteria:

- Histological confirmation of non-small cell cancer will be required by either biopsy or cytology
- Eligible patients must have appropriate staging studies identifying them as specific subsets of the revised IASLC stage IA or IB
- A PET/CT scan is required
- Be considered a reasonable candidate for surgical resection of the primary tumor
- Be at least 18 years of age
- Zubrod performance status must be 0-2
- Mandatory staging studies (PET-CT, CT, Chest X-ray, MRI/CT brain if signs/symptoms of brain metastases) must be done within 8 weeks prior to study entry
- Sign a study-specific consent form
- Be willing to use adequate contraceptive precautions

Compensation:

- Participants will receive a \$100 check for each completed clinical study milestones (study enrollment and randomization, treatment, and yearly follow up for five years)

Procedures:

- Laboratory studies include a CBC with differential, platelet count, LFTs, electrolytes, creatinine
- Chest X-ray, MRI or brain CT scans if signs/symptoms of brain metastases noted
- A PET/CT scan within 8 weeks prior to definitive treatment is required
- A quantitative lung perfusion study recommended to evaluate patient's tolerance for surgical resection
- First follow up will be at 4-6 weeks after treatment consisting of a history and physical exam and CXR if clinically indicated
- CT scan at the 6 month follow up for all patients randomized to surgery arm
- PFTs at the 12 month follow up period
- CT scans at the 12 month, 18 month, 24 month, 3 year, 4 year and 5 year follow-up



Benefits for Patients:

- Opportunity to receive a non-surgical treatment for lung cancer
- May receive surgery if tumor recurs following CK
- May receive additional CK treatments if needed in the future for either surgery or CK patients

Protocol #2007-0870

Principal Investigator: Jack Roth, MD

Schedule an appointment or make referral online at <https://my.mdanderson.org> or call 713-745-5353

For more information about the study, contact the Thoracic & Cardiovascular Surgery Research Nurses at 713-563-9152, 713-563-9155, 713-563-9156, or at TCVS_ClinicalTrials@mdanderson.org

For information on related articles or references for this study, visit <http://physicianrelations.org> or <http://clinicaltrials.gov/ct2/show/NCT00840749>

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