CALGB-140503

A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (≤ 2 cm) Peripheral Non-Small Cell Lung Cancer

ClinicalTrials.gov Identifier: NCT00499330

Study Background

Trial Description

RATIONALE: Wedge resection or segmentectomy may be less invasive types of surgery than lobectomy for non-small cell lung cancer and may have fewer side effects and improve recovery. It is not yet known whether wedge resection or segmentectomy are more effective than lobectomy in treating stage IA non-small cell lung cancer.

PURPOSE: This randomized phase III trial is studying different types of surgery to compare how well they work in treating patients with stage IA non-small cell lung cancer.

Arms:

Arm A: (Other): Patients undergo a standard operation for lung cancer called a lobectomy.

Arm B: (Experimental): Patents undergo a limited resection (segmentectomy or wedge resection), which a smaller portion of the lung is removed.

Objectives:

- OUTLINE: This is a multicenter, randomized study. Patients are stratified according to tumor size (< 1 cm vs 1-1.5 cm vs > 1.5-2.0 cm) (based on the maximum dimension determined from the preoperative CT scan), histology (squamous cell carcinoma vs adenocarcinoma vs other), and smoking status (never smoked [smoked < 100 cigarettes over lifetime] vs former smoker [smoked > 100 cigarettes AND quit ≥ 1 year ago] vs current smoker [quit < 1 year ago or currently smokes]). Patients are randomized to 1 of 2 treatment arms. For more information, please see the Arms section.
- Primary Objective: To determine whether DFS after sublobar resection (segmentectomy or wedge) is non-inferior to that after lobectomy in patients with small peripheral ≤ 2 cm) NSCLC.

- Secondary Objectives:

  1. To determine whether overall survival (OS) (after sublobar resection) is non-inferior to that after lobectomy.

  2. To determine the rates of loco-regional and systemic recurrence (exclusive of second primaries) after lobar and sublobar resection.

  3. To determine the difference between the two arms of the study in pulmonary function as determined by expiratory flow rates measured at 6 months post-operatively.

  4. Imaging Substudy: To explore the relationship between characteristics of the primary lung cancer, as revealed by pre-operative CT and PET imaging, and outcomes; a determination of the false-negative rate of the pre-operative PET scan for identification of involved hilar and mediastinal lymph nodes; and an assessment of the utility of annual follow-up CT imaging after surgical resection of small stage IA NSCLC. After completion of study treatment, patients are followed up every 6 months for 2 years and then annually for 5 years.

Study Milestones:

Start date: October 2007

Primary Completion Date: April 2024

Publication Information:

Analysis Type: Primary

PubMed ID: 36780674

Citation: N Engl J Med 2023; 388:489-498 DOI: 10.1056/NEJMoa2212083

Associated Datasets: NCT00499330-D1-Dataset.csv (final_analysis)

Dataset Information:

Dataset Name: NCT00499330-D1-Dataset.csv (final_analysis)

Description: Dataset NCT00499330-D1-Dataset.csv (final_analysis) is one of 1 dataset associated with PubMed ID 36780674. This dataset contains data presented in the baseline characteristics table, primary analysis, the first three objectives of the secondary analysis, the per-protocol analysis, and an additional site analysis.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

NCT00499330-D1-Dataset.csv (final_analysis) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Institution ID	inst_id		
Accrual for Institution ID	inst_accrual		
Arm	treat_assigned	Limited resection, Lobectomy	
Age (years)	age		
Gender	sex_id	Female, Male	
Race	race_id	American Indian or Alaska Native, Asian, Black or African American, More than one race, Not Reported, Unknown, White	
Tumor location area	primarytum	Left lower lobe, Left upper lobe, Lingula, Right lower lobe, Right middle lobe, Right upper lobe	
ECOG Performance	ps	0, 1, 2	

LABEL	NAME	ELEMENTS	COMMENTS
status			
Smoking Status	strat_smoke	Current, Former, Never	
Tumor Size (cm)	strat_tumsz	<1.0, >1.5-2.0, 1.0-1.5	
Histology	strat_histo	Adenocarcinoma, Other, Squamous Cell Carcinoma	
Surgical procedure received by patient	sproc_actual	Lobectomy, Segmentectomy, Wedge resection	Two limited resection arm patients who underwent lobectomy were not originally classified as converted (procedure not matching arm) and were included in the per-protocol analysis.
Did patient meet intra-operative eligibility criteria	inop_elig	No, Yes	Split between two arms is opposite what was originally written in main manuscript (15 lobar, 12 sublobar). Used in conjunction with sproc_actual and treat_assigned to determine per-protocol population.
Did patient experience relapse/recurrence of disease?	relapse	No, Yes	
Type of recurrence	recurr_type	Any distant, Locoregional, None, Regional only	
New primary lung cancer	new_prilung	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Cause of death	causedth	Cause Unknown, Complications of protocol surgery (within 30 days after surgery), Due to other cause, Due to this disease	
Follow-up Status	status_fu	Confirmed Withdrawl/Lost to follow-up, Death, Reached max follow-up time, Still in follow-up	Patients who were confirmed lost to follow-up were not originally included in the 'early dropout or withdrawal' group. These patients are now included in this group, so totals vary slightly from original consort diagram.
Confirmed Withdrawal	early_wd	No, Yes	
Confirmed Lost to Follow-up	lfu_stat	No, Yes	
Disease-free Survival follow-up time (years)	dfsyears		

LABEL	NAME	ELEMENTS	COMMENTS
Disease-free Survival event	dfscens	0=No, 1=Yes	Single lobectomy patient was missing date of relapse, and this caused them to be missing from event count. Date has since been added in, leading to slight change in their time for DFS & RFS in addition to DFS event count.
Overall Survival follow-up time (years)	osyears		
Overall Survival event	oscens	0=No, 1=Yes	
Recurrence-free Survival follow-up time (years)	rfsyears		
Recurrence-free Survival event	rfscens	0=No, 1=Yes	
Competing risks death follow-up time (years)	cifyears		
Competing Risks death event	cifcens	0=Alive, 1=Lung cancer related death, 2=Death from other cause	
Baseline FEV1 (%)	fev1_bsl		
6 months FEV1 (%)	fev1_v1		

LABEL	NAME	ELEMENTS	COMMENTS
Change in FEV1 (%) from Baseline	diff_fev1		
Baseline FVC (%)	fvc_bsl		
6 months FVC (%)	fvc_v1		
Change in FVC (%) from Baseline	diff_fvc		