CALGB-30607

Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib (NSC #736511) as Maintenance Therapy in Non-progressing Patients Following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB / IV Non-small Cell Lung Cancer

ClinicalTrial.gov Identifier: NCT00693992

Study Background

Trial Description

This randomized phase III trial studies sunitinib malate to see how well it works when given as maintenance therapy (meaning it is approved for treatment after chemotherapy) in patients with stage IIIB-IV non-small cell lung cancer who have responded to prior treatment with combination chemotherapy. Sunitinib malate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth and by blocking the growth of new blood vessels necessary for tumor growth. It is not yet known whether sunitinib malate is effective in helping tumors continue to shrink or stop growing.

Arms:

Arm I (sunitinib malate): (Experimental): Patients receive sunitinib malate 37.5 mg PO once daily on days 1-21. Courses repeat every 21 days in the absence of disease progression or unacceptable toxicity.

Arm II (placebo): (Placebo Comparator): Patients receive placebo 37.5 mg PO once daily on days 1-21. Courses repeat every 21 days in the absence of disease progression or unacceptable toxicity.

Objectives:

- PRIMARY OBJECTIVES:

  I. To evaluate the effect of sunitinib (sunitinib malate) compared to placebo on progression-free survival (PFS) in advanced non-small cell lung cancer (NSCLC) patients who have had either stable or responding disease over the course of their initial 4 cycles of platinum-based therapy.

- SECONDARY OBJECTIVES:

  I. To evaluate the toxicity of sunitinib compared to placebo in the maintenance setting.

  II. To evaluate the additional response rate as a result of sunitinib in this setting.

  III. To assess the impact of sunitinib on overall survival compared to the placebo arm.

  IV. To assess the impact of sunitinib on delaying the time to deterioration in quality of life and symptom progression compared to placebo using the European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30) and Lung Cancer Module (LC13).

  V. To assess vascular endothelial growth factor (VEGF) haplotypes in advanced non-small cell lung cancer and sunitinib maintenance.

- OUTLINE: Patients are randomized to 1 of 2 treatment arms.
- ARM I: Patients receive sunitinib malate orally (PO) once daily (QD) on days 1-21. Courses repeat every 21 days in the absence of disease progression or unacceptable toxicity.
- ARM II: Patients receive placebo PO QD on days 1-21. Courses repeat every 21 days in the absence of disease progression or unacceptable toxicity.
- After completion of study treatment, patients are followed up every 3 months for 1 year, every 6 months for 1 year, and then periodically for 3 years.

Study Milestones:

Start date: June 2008

Primary Completion Date: November 2013

Publication Information:

Analysis Type: Primary

Pubmed ID: 28161554

Citation: J Thorac Oncol vol 12 (5) 843-849 2017

Associated Datasets: NCT00693992-D1-Dataset.csv (clinical), NCT00693992-D2-Dataset.csv (toxicity), NCT00693992-D3-Dataset.csv (qol)

Dataset Information:

Dataset Name: NCT00693992-D1-Dataset.csv (clinical)

Description: Dataset NCT00693992-D1-Dataset.csv (clinical) is one of 3 datasets associated with PubMed ID 28161554. This dataset contains information that will allow you to reproduce the baseline characteristics table and primary analysis.

NCT00693992-D1-Dataset.csv (clinical) Data Dictionary:

LABEL	NAME	elements	comments
PATIENT_ID	patid		
RACE_ID	RACE_ID	White, Black or African American, Asian, More than one race, Unknown, American Indian or Alaska Native	
Age (yrs)	age		
TREAT_ASSIGNED	arm	Sunitinib, Placebo	'Arm I' and 'Arm II' from the protocol and background information are synonymous with 'Sunitinib' and 'Placebo', respectively.
ECOG performance status (stratification factor)	PSf	0, 1	
Clinical stage (stratification factor)	stagef	IV, IIIB	
Prior use of bevacizumab (stratification factor)	prbevf	No, Yes	
Gender (stratification factor)	genderf	Male, Female	
Reasons for off protocol treatment	offtrt_rx	Adverse event, PD/relapse during active tx, Refusal after beginning protocol tx, Off study prior to beginning protocol tx, Alternative therapy,	Missing=Unknown or still on treatment at time of publication.

		Other, Death on study, Patient off-tx for other complicating disease	
Best overall response to protocol treatment	resp	Stable, Progression, Insufficient evaluation, Partial response, Complete response	Missing=Off study prior to beginning protocol tx and never assessed
Smoking history	PRSMOKE	Past, Current, Never	
HISTOLOGY	HISTOLOGY	Adenocarcinoma (including BAC), Squamous cell carcinoma (epidemoid), Large cell anaplastic carcinoma (including giant and clear cell), Undifferentiated non-small cell, Other	
Survival Status (1= Died, 0 = Alive)	survcens	1, 0	
Overall survival time from the date of registration in months	survtime		
Indicator of Progression/death status (1 = progression or death, 0 = censored)	failcens	1, 0	
Progression-free survival time from the date of registration in months	failtime		
Squamous (Y/N)	sqc	Non squamous cell carcinoma, Squamous cell carcinoma	