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: Journal of Thoracic Oncology Vol. 12 No. 5: 843-849

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

Dataset Information:

Dataset Name: NCT00693992-D3-Dataset.csv (calgb30607qol)

Description: Dataset NCT00693992-D3-Dataset.csv (calgb30607qol) is one of 3 datasets associated with PubMed ID 28161554. This dataset contains information that will allow you to reproduce the QOL portion of the manuscript.

Due to data cleaning efforts, values may contain slight discrepancies from that reported in Table 1 of the Supplemental Materials. In addition, it was reported in the manuscript that n=179 patients reported QOL data for at least one time point. It is true that n=179 patients consented to participate to the QOL portion of the study and provided baseline information; however, 4 patients did not provide questionnaire data for analysis.

NCT00693992-D3-Dataset.csv (calgb30607qol) Data Dictionary:

LABEL	NAME	elements	comments
PATIENT_ID	patid		
Arm	TREAT_ASSIGNED	Sunitinib, Placebo	Missing=unknown/ not reported
QLQ C30: Global subscale Change from Baseline to 3 Months	m3_global100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Global subscale Month 3 score	month3_global100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Cognition subscale Change from Baseline to 3 Months	m3_cog100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Cognition subscale Month 3 score	month3_cog100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Fatigue subscale Baseline score	base_fat100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Nausea and Vomitting subscale Change from Baseline to 3 Months	m3_nav100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Nausea and Vomitting subscale Month 3 score	month3_nav100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Dyspnea subscale Change from Baseline to 6 Months	m6_dysp100	Continuous (-100 - 100)	Missing=unknown/ not reported

QLQ C30: Appetite subscale Change from Baseline to 3 Months	m3_app100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Appetite subscale Month 3 score	month3_app100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Diarrhea subscale Change from Baseline to 3 Months	m3_diar100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Diarrhea subscale Month 3 score	month3_diar100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Diarrhea subscale Month 6 score	month6_diar100	Continuous (0-100)	Missing=unknown/ not reported
QLQ C30: Financial difficulties subscale Change from Baseline to 3 Months	m3_finan100	Continuous (-100 - 100)	Missing=unknown/ not reported
QLQ C30: Financial difficulties subscale Baseline score	base_finan100	Continuous (0-100)	Missing=unknown/ not reported
EQ-5D Index Change from Baseline to 3 Months	m3_eq_index	Continuous (-1-1)	Missing=unknown/ not reported
EQ-5D Index Month 3 score	month3_eq_index	Continuous (0-1)	Missing=unknown/ not reported
LC13: Sore mouth or tongue Change from Baseline to 3 Months	m3_eo010	Continuous (-4 -4)	Missing=unknown/ not reported
LC13: Sore mouth or tongue Month 3 score	month3_eo010	Continuous (0-4)	Missing=unknown/ not reported
LC13: Trouble swallowing Month 3 score	month3_eo011	Continuous (0-4)	Missing=unknown/ not reported
LC13: Helpfulness of pain medication Change from Baseline to 3 Months	m3_eo019	Continuous (-4 -4)	Missing=unknown/ not reported
LC13: Dyspnea subscale Month 3 score	month3_dyspnea	Continuous (0-4)	Missing=unknown/ not reported
Employment status	employ	Retired, Employed, Disabled, Other	Missing=unknown/ not reported
Age (years)	age		
Did the patient provide QOL data at baseline?	baseline	1=Yes, Missing= No	

Did the patient provide QOL data at month 3?	month3	1=Yes, Missing= No	The manuscript reports n=121 patients and this data provides information from n=124 at this time point due to updated data.
Did the patient provide QOL data at month 6?	month6	1=Yes, Missing= No	