

CALGB-30504

Combination Chemotherapy With or Without Maintenance Sunitinib Malate (NSC 736511) For Untreated Extensive Stage Small Cell Lung Cancer: A Phase IB/Randomized Phase II Study

ClinicalTrial.gov Identifier: NCT00453154

Study Background

Trial Description

This partially randomized phase I/II trial studies the side effects and best dose of sunitinib malate and to see how well it works when given together with cisplatin or carboplatin and etoposide in treating patients with extensive-stage small cell lung cancer. Drugs used in chemotherapy, such as cisplatin, carboplatin, and etoposide, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Sunitinib malate may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth and by blocking blood flow to the tumor. It is not yet known whether cisplatin or carboplatin and etoposide are more effective when given with or without sunitinib malate in treating small cell lung cancer.

Arms:

Arm I (Combination Chemotherapy + Sunitinib Maintenance): (Experimental): Participants will receive the following combination chemotherapy for 4-6 cycles (21 days):

- Cisplatin 80 mg/m² by IV over 1 hour on day 1 every cycle OR Carboplatin AUC = 5* by IV Etoposide 100 mg/m² by IV over 1 hour on days 1, 2, and 3 every cycle
- Maintenance: Following 4-6 cycles of combination chemotherapy, start sunitinib at 150 mg on day 1, then 37.5 daily until disease progression.

Arm II (Combination Chemotherapy + Placebo Maintenance): (Active Comparator): Participants will receive the following combination chemotherapy for 4-6 cycles (21 days):

- Cisplatin 80 mg/m² by IV over 1 hour on day 1 every cycle OR Carboplatin AUC = 5* by IV Etoposide 100 mg/m² by IV over 1 hour on days 1, 2, and 3 every cycle
- Maintenance: Following 4-6 cycles of combination chemotherapy, start placebo at 150 mg on day 1, then 37.5 daily until disease progression.

Objectives:

PRIMARY OBJECTIVES:

1. To determine the phase II dose for sunitinib (sunitinib malate) combined with cisplatin

and etoposide. (Phase IB)

2. To compare the progression-free survival of patients with extensive stage small cell lung cancer treated with cisplatin or carboplatin and etoposide followed by maintenance sunitinib to patients receiving the same chemotherapy followed by placebo. (Phase II)

SECONDARY OBJECTIVES:

- I. To assess the single agent response rate for sunitinib given as monotherapy after chemotherapy. (Phase II)
- II. To assess the overall survival of patients treated with cisplatin or carboplatin and etoposide followed by sunitinib. (Phase II)
- III. To evaluate the toxicity and tolerability of maintenance sunitinib after cisplatin or carboplatin and etoposide. (Phase II)
- IV. To determine the association between vascular endothelial growth factor (VEGF) plasma levels and tumor response. (Phase II)

Publication Information:

Analysis Type: Primary

PubMed ID: 25732163

Citation: J Clin Oncol. 2015 May 20;33(15):1660-5. doi: 10.1200/JCO.2014.57.3105. Epub 2015 Mar 2.

Associated Datasets: NCT00453154-D1-Dataset (ae), NCT00453154-D2-Dataset (Clinical)

Dataset Information:

Dataset Name: NCT00453154-D2-Dataset.csv (clinical)

Description: Dataset NCT00453154-D2-Dataset.csv (clinical) is one of 2 datasets associated with PubMed ID 25732163. This dataset contains information for the baseline characteristics and outcome data.

Unless indicated, missing values indicate the data was not collected.

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).

NCT00453154-D2-Dataset.csv (clinical) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient Reference	patid		De-identified patient reference
Gender	sex	1 = Male 2 = Female	
Race	race	1 = White 3 = Black or African American	
Arm Assignment	arm	1 = Sunitinib 2 = Placebo	
Began treatment with cisplatin vs. treatment with carboplatin (stratification factor)	straf_chemo	1 = Cisplatin 2 = Carboplatin	
< 6 cycles vs. 6 cycles (stratification factor)	straf_cycle	0 = less than 6 cycles 1 = 6 cycles	
# cycles of maintenance therapy	cycle_maint	Continuous	
# cycles cross-over tx received	cycle_cross	Missing = Did not receive crossover	
Best response to maintenance therapy	br_maint	5 = CR 6 = PR 8 = Stable 9 = Progression Missing = Was not assessed at maintenance	

Off treatment reasons	offtrt_rx	2 =Disease Progression 4 = AE 5 = Death on study 6 = Refused further protocol TX, but consented to be followed 7 = Refused further protocol TX and withdrew consent to be followed 8 = Other medical illness 12 = Other	
ECOG performance status at registration	PS	2, 0, 1	
Received (Y/N) Prophylactic Cranial Irradiation (PCI)	pci	1 = No 2 = Yes	
Group # cycles of maintenance therapy in three categories	cycle_maint2	1 = 1 to 4 cycles 2 = 5 to 8 cycles 3 = greater than 8 cycles Missing = Received No Maintenance	
Overall survival status	survcens	0 = Alive 1 = Died	
Progression status	failcens	0 = No progression 1 = Progressed	
Overall survival time from randomization (months)	survtime		
Progression-free survival time from randomization (months)	failtime		
Overall survival time from registration (months)	survtime2		
Progression-free survival time from registration (months)	failtime2		
Progression status on cross-over to Sunitinib (13	pd2	0 = No progression 1 = Progressed	If missing, then are not cross-over

evaluable cross-over patients)			evaluable patients.
Progression-free survival time in months (13 evaluable cross-over patients)	pfs2		If missing, then are not cross-over evaluable patients.
Crossover patients evaluable	cross_eval	1 = Yes 0 = No	
Age at registration (years)	age		
Response after induction chemotherapy	br_induct	PR/CR, SD	
Sunitinib dose modification	sundosemod	1 = Yes	
Grade 3 or higher adverse event during crossover Sunitinib	cross_ae3p	1 = Grade 3+ 0 = Grade < 3 (evaluable)	
Evaluable for adverse events for maintenance therapy patients	eval_ae_maint	1 = Yes	
SD for crossover to sunitinib	sd_cross	1 = Yes	