CALGB-80802

Phase III Randomized Study of Sorafenib Plus Doxorubicin Versus Sorafenib in Patients With Advanced Hepatocellular Carcinoma (HCC)

ClinicalTrial.gov Identifier: NCT01015833

Study Background

Trial Description

This randomized phase III trial studies sorafenib tosylate and doxorubicin hydrochloride to see how well they work compared with sorafenib tosylate alone in treating patients with liver cancer that has spread to nearby tissue or lymph nodes or has spread to other places in the body. Sorafenib tosylate 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. Drugs used in chemotherapy, such as doxorubicin hydrochloride, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. It is not yet known whether giving sorafenib tosylate together with doxorubicin hydrochloride is more effective than sorafenib tosylate alone in treating liver cancer.

Arms:

Arm I (doxorubicin hydrochloride, sorafenib tosylate): (Experimental): Patients receive doxorubicin hydrochloride IV on day 1 and sorafenib tosylate PO QD or BID on days 1-21. Treatment repeats every 21 days for 6 courses in the absence of disease progression or unacceptable toxicity. After 6 courses, patients may continue to receive sorafenib tosylate PO QD or BID in the absence of disease progression or unacceptable toxicity.

Arm II (sorafenib tosylate): (Experimental): Patients receive sorafenib tosylate PO QD or BID on days 1-21. Courses repeat every 21 days in the absence of disease progression or unacceptable toxicity.

Objectives:

PRIMARY OBJECTIVES:

I. Compare the overall survival (OS) of patients treated with sorafenib (sorafenib tosylate) and doxorubicin (doxorubicin hydrochloride) to that of those treated with sorafenib.

SECONDARY OBJECTIVES:

I. Compare time to progression (TTP) of patients treated with sorafenib and doxorubicin to that of those treated with sorafenib.

II. Compare progression-free-survival (PFS) of patients treated with sorafenib and doxorubicin to that of those treated with sorafenib.

III. Compare tumor response using Response Evaluation Criteria in Solid Tumors (RECIST) criteria of patients treated with sorafenib and doxorubicin to that of those treated with sorafenib.

OUTLINE: Patients are randomized to 1 of 2 treatment arms.

Study Milestones:

Primary Completion Date: May 21, 2015

Publication Information:

Analysis Type: Primary

PubMed ID: 31486832

Citation: JAMA Oncol. 2019 Sep 5;5(11):1582-1588. doi: 10.1001/jamaoncol.2019.2792.

Associated Datasets: NCT01015833-D1-Dataset.csv (nctn_d1)

Dataset Information:

Dataset Name: NCT01015833-D1-Dataset.csv (nctn_d1)

Description: Dataset NCT01015833-D1-Dataset.csv (nctn_d1) is the only dataset associated with PubMed ID 31486832. This dataset contains the information for the entire primary 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.

NCT01015833-D1-Dataset.csv (nctn_d1) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient identifier	patid		
Gender	SEX_ID	Male, Female	
Race	RACE_ID	0="Unknown" 1="White" 3="Black or African American" 4="Asian" 6="American Indian or Alaska Native" 13="Not Reported"	
ECOG PS	PERFORMANCE_ID	0, 1, 2	
Treatment Arm	TREAT_ASSIGNED	A="Doxorubicin + sorafenib" B="Sorafenib alone"	
Age (years)	age		
Extent of Disease	dis_ext	1="Locally Advanced" 2="Metastatic"	

LABEL	NAME	ELEMENTS	COMMENTS
Off Treatment Reason	OFFTRT	AE, Patient withdrawal prior to beginning treatment, Death on Study, Disease Progression, Patient withdrawal after beginning treatment, Alternative Therapy, Other, Ineligible-Not Included, Other complicating disease	Missing indicates patient was still on treatment at time of manuscript preparation. Off treatment reasons were re-categorized for simplicity in the manuscript. The data in this dataset represents the data submitted by the treating site.
Histologic Grade	TUMGR	1="Grade cannot be assessed" 2="Well differentiated" 3="Moderately Differentiated" 4="Poorly Differentiated" 5="Undifferentiated"	Missing indicates data was not collected
Hepatitis Status	HEPATITIS	Hepatitis C, No Hepatitis, Hepatitis B and C, Hepatitis B	Missing indicates the patient did not have hepatitis.
Tumor Response	TUMRESP	5=CR 6=PR 8=SD 9=PD 10=Not Evaluable	Missing indicates data was not collected
Time to Progression Status	pd_stat	1=Event 0=Censor	Progression was counted as an event
PFS Stat	pf_stat	1=Event 0=Censor	Death or Progression was counted as an event
PFS Time (Months)	pf_time		

LABEL	NAME	ELEMENTS	COMMENTS
Time to Progression (Months)	pd_time		
OS Stat	dead	1=Death 0=Censor	
OS Time (Months)	fu_time		
Reverse Kaplan Meier Survival Stat	fu_stat	0= Death 1= Censor	
Max Grade Left Ventricular Systolic Dysfunction	ae1	1, 2, 3, 4	Missing indicates the patient did not report this type of AE.
Max Grade Ejection Fraction Decreased	ae2	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Hypothyroidism	ae3	1, 2	Missing indicates the patient did not report this type of AE.
Max Grade Abdominal Pain	ae4	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Diarrhea	ae5	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Mucositis Oral	ae6	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Nausea	ae7	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Fatigue	ae8	1, 2, 3, 4	Missing indicates the patient did not report this type of AE.
Max Grade Neutrophils Count Decreased	ae9	1, 2, 3, 4	Missing indicates the patient did not report this type of AE.

LABEL	NAME	ELEMENTS	COMMENTS
Max Grade Platelets Count Decreased	ae10	1, 2, 3, 4	Missing indicates the patient did not report this type of AE.
Max Grade Hematuria	ae11	1, 2	Missing indicates the patient did not report this type of AE.
Max Grade Epistaxis	ae12	1, 2	Missing indicates the patient did not report this type of AE.
Max Grade Palmar-Plantar Erythro-Dysesthesia	ae13	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Skin Ulceration	ae14	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Hypertension	ae15	1, 2, 3	Missing indicates the patient did not report this type of AE.
Max Grade Other AE	ae16	1, 2, 3, 4, 5	
Max Grade Heme	ae_heme	1, 2, 3, 4	
Max Grade Non-Heme	ae_nonheme	1, 2, 3, 4, 5	
Evaluable for AE	ae_eval	1 = Evaluated for adverse events	Missing indicates the patient was not evaluated for adverse events.
Max Grade Overall	ae_ovr	1, 2, 3, 4, 5	Missing indicates the patient either was not evaluated for adverse events (ae_eval is missing) OR patient was evaluable but did not report any adverse events
Relation	RELATION_ID	1=Unrelated 2=Unlikely 3=Possible 4=Probably 5=Definite	Relation for Grade 5 Adverse Events. Missing indicates event was not grade 5.

LABEL	NAME	ELEMENTS	COMMENTS
Baseline, AFP (ng/mL)	AFP		
Cycles of Doxorubicin	cycles		
Doxorubicin Total Dose (mg)	dox_received		
Sorafenib Total Daily Dose (mg)	sora_daily		
Weeks of Sorafenib	tx_wks		
Prior Surgery	PRSURG	No Yes	
Prior Locoregional Therapy	PRREGCHEMO	No Yes	
Prior Adjuvant Therapy	PRADJCHEMO	No Yes	