CALGB-90601

A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients With Advanced Transitional Cell Carcinoma

ClinicalTrials.gov Identifier: NCT00942331

Study Background

Trial Description

This randomized phase III trial studies gemcitabine hydrochloride, cisplatin, and bevacizumab to see how well they work compared with gemcitabine hydrochloride and cisplatin in treating patients with urinary tract cancer that has spread to other places in the body. Drugs used in chemotherapy, such as gemcitabine hydrochloride and cisplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Immunotherapy with bevacizumab, may induce changes in body's immune system and may interfere with the ability of tumor cells to grow and spread. It is not yet known whether gemcitabine hydrochloride and cisplatin are more effective when given with or without bevacizumab in treating patients with urinary tract cancer.

Arms:

Arm I (gemcitabine hydrochloride, cisplatin, placebo): (Active Comparator): Patients receive gemcitabine hydrochloride IV over 30 minutes on days 1 and 8 and cisplatin IV and placebo IV over 30-90 minutes on day 1. Treatment repeats every 21 days for 6 cycles in the absence of disease progression or unacceptable toxicity. Patients then receive placebo IV over 30-90 minutes every 21 days in the absence of disease progression or unacceptable toxicity.

Arm II (gemcitabine hydrochloride, cisplatin, bevacizumab): (Experimental): Patients receive gemcitabine hydrochloride and cisplatin as in arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment repeats every 21 days for 6 cycles in the absence of disease progression or unacceptable toxicity. Patients then receive bevacizumab IV over 30-90 minutes every 21 days in the absence of disease progression or unacceptable toxicity.

Objectives:

PRIMARY OBJECTIVES:

I. To determine if patients with advanced transitional cell carcinoma treated with bevacizumab, gemcitabine hydrochloride (gemcitabine) and cisplatin will have increased overall survival when compared to patients treated with gemcitabine, cisplatin, and placebo.

SECONDARY OBJECTIVES:

I. To compare the progression-free survival of these two regimens in patients with advanced transitional cell carcinoma.

II. To compare the proportion of patients who experience an objective response on each regimen.

III. To compare the grade 3 and greater toxicities in patients treated on the two regimens.

Study Milestones:

Start date: July 15, 2009

Primary Completion Date: November 2, 2018

Publication Information:

Analysis Type: Primary

PubMed ID: 33989025

Citation: J Clin Oncol. 2021 May 14;JCO2100286. doi: 10.1200/JCO.21.00286.

Associated Datasets: NCT00942331-D1-Dataset.csv (pt_all), NCT00942331-D2-Dataset.csv (dosemod_all), NCT00942331-D3-Dataset.csv (ae_all)

Dataset Information:

Dataset Name: NCT00942331-D3-Dataset.csv (ae_all)

Description: Dataset NCT00942331-D3-Dataset.csv (ae_all) is one of 3 datasets associated with PubMed ID 33989025. This dataset contains adverse event information.

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.

NCT00942331-D3-Dataset.csv (ae_all) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Adverse Event Term	aecat		
Grade 3 Plus Adverse Event	grade3plus	0=No, 1=Yes	
Hematologic Adverse Event	heme	0=No, 1=Yes	Febrile Neutropenia is counted as hematologic to match the manuscript even though it is a non-hematologic adverse event.