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:

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-D2-Dataset.csv (dosemod_all)

Description: Dataset NCT00942331-D2-Dataset.csv (dosemod_all) is one of 3 datasets associated with PubMed ID 33989025. This dataset contains dose modification reasons for all patients with at least one dose reduction or delay. There is also a variable distinguishing the dose modification between cisplatin and gemcitabine.

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-D2-Dataset.csv (dosemod_all) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Dose Reduction reason	reduc_mod	Hematologic toxicity, Renal toxicity, GI toxicity, Infection/fever, Other, CNS toxicity, Change in BSA, Hypersensitivity	
Dose Reduction Agent	reduc_agent	Gemcitabine, Cisplatin	
Dose Delay reason	delay_mod	Hematologic toxicity, Renal toxicity, Scheduling (e.g. physician vacation, patient schedule, holiday, vacation, etc.), Other, Infection/fever, Hypersensitivity, GI toxicity, CNS toxicity, Patient refusal/noncompliance, Change in BSA, Hypertension	
Dose Delay Agent	delay_agent	Gemcitabine, Cisplatin	