CALGB-80702

A Phase III Trial of 6 Versus 12 Treatments of Adjuvant FOLFOX Plus Celecoxib or Placebo for Patients with Resected Stage III Colon Cancer

ClinicalTrial.gov Identifier: NCT01150045

Study Background

Trial Description

PURPOSE: This randomized phase III trial is studying giving oxaliplatin, leucovorin calcium, and fluorouracil together to compare how well they work when given together with or without celecoxib in treating patients with stage III colon cancer previously treated with surgery.

Arms:

Arm A - FOLFOX and placebo (12 treatments): (Active Comparator): Patients receive FOLFOX every 2 weeks plus placebo every day for 12 treatments (24 weeks). Each 2-week period is called a cycle. FOLFOX includes oxaliplatin, leucovorin and 5-FU. Then, patients receive placebo alone every day for 3 years total.

Arm B - FOLFOX and celecoxib (12 treatments): (Experimental): Patients receive FOLFOX every 2 weeks plus celecoxib every day for 12 treatments (24 weeks). Each 2-week period is called a cycle. FOLFOX includes oxaliplatin, leucovorin and 5-FU. Then, patients receive celecoxib alone every day for 3 years total.

Arm C - FOLFOX and placebo (6 treatments): (Active Comparator): Patients receive FOLFOX every 2 weeks plus placebo every day for 6 treatments (12 weeks). Each 2-week period is called a cycle. FOLFOX includes oxaliplatin, leucovorin and 5-FU. Then, patients receive placebo alone every day for 3 years total.

Arm D - FOLFOX and celecoxib (6 treatments): (Experimental): Patients receive FOLFOX every 2 weeks plus celecoxib every day for 6 treatments (12 weeks). Each 2-week period is called a cycle. FOLFOX includes oxaliplatin, leucovorin and 5-FU. Then, patients receive celecoxib alone every day for 3 years total.

Objectives:

Primary objective:

1. To compare disease-free survival of patients with stage III colon cancer randomized to standard chemotherapy only FOLFOX or standard chemotherapy FOLFOX with 3 years of celecoxib 400 mg daily.

Secondary objectives:

1. To contribute to an international prospective pooled analysis that will compare disease-free survival of patients with stage III colon cancer randomized to 6 treatments of adjuvant FOLFOX chemotherapy or 12 treatments of adjuvant FOLFOX chemotherapy.
2. To compare overall survival of patients with stage III colon cancer randomized to standard chemotherapy only (FOLFOX) or standard chemotherapy (FOLFOX) with 3 years of celecoxib 400 mg daily.
3. To contribute to an international prospective pooled analysis that will compare overall survival of patients with stage III colon cancer randomized to 6 treatments of adjuvant FOLFOX chemotherapy or 12 treatments of adjuvant FOLFOX chemotherapy or 12 treatments of adjuvant FOLFOX chemotherapy.
4. To assess toxicities of celecoxib as maintenance adjuvant therapy in patients with stage III colon cancer.
5. To assess differences in cardiovascular-specific events with celecoxib versus placebo in a population of stage III colon cancer survivors.
6. To evaluate differences in toxicities, particularly cumulative peripheral neuropathy, for patients treated with 6 treatments of FOLFOX compared to those treated with 12 treatments of FOLFOX. After completion of study therapy, patients are followed up every 6 months for up to 6 years.

Study Milestones:

Start date: June 2010

Primary Completion Date: February 28, 2020

Publication Information:

Analysis Type: Primary

PubMed ID: 33821899

Citation: JAMA. 2021 Apr 6;325(13):1277-1286. doi: 10.1001/jama.2021.2454.

Associated Datasets:

NCT01150045-D1-Dataset.csv (Figure1),

NCT01150045-D2-Dataset.csv (Figure2),

NCT01150045-D3-Dataset.csv (Table1),

NCT01150045-D4-Dataset.csv (Table2)

Dataset Information:

Dataset Name: NCT01150045-D4-Dataset.csv (Table2)

Description: Dataset NCT01150045-D4-Dataset.csv (Table2) is one of 4 datasets associated with PubMed ID 33821899. This dataset contains the data presented in the adverse events table (Table 2). The data is one row-per-patient for each treatment phase. The first treatment phase is while FOLFOX is given with Celecoxib or Placebo. The second treatment phase is after completing/ending FOLFOX therapy and continuing with Celecoxib or Placebo. The maximum grade variables are all possibly, probably or definitely related to treatment.

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).

Adverse events recorded on CRF utilized CTCAE version 3.0 and adverse events reported through CTEP-AERs utilized CTCAE version 4.0. All adverse event variables were graded on a scale of 0 through 5 (or less as applicable to certain adverse events). Missing values should be regarded as true missing and not grade 0 values. Patients that were not treated will have all missing values. Patients can have missing data for individual adverse events if either grade or attribution information is incomplete for the specified adverse event.

NCT01150045-D4-Dataset.csv (Table2) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Treatment Phase	subset	During FOLFOX Therapy, After FOLFOX Therapy	
Patient ID	patid		
Assigned Oral Agent	placebo	Celecoxib, Placebo	
Creatinine Maximum Grade Possibly Related	creatinine		
Cerebral Ischaemia Maximum Grade Possibly Related	cere_ischemia		
Diarrhea Maximum Grade Possibly Related	diarrhea		
Fatigue Maximum Grade Possibly Related	fatigue		

LABEL	NAME	ELEMENTS	COMMENTS
Gastric Ulcer Maximum Grade Possibly Related	gastric_ulcer		
Gastritis Maximum Grade Possibly Related	gastritis		
Hypertension Maximum Grade Possibly Related	hypertension		
Myocardial Ischaemia Maximum Grade Possibly Related	myocardia_ischemia		
Nausea Maximum Grade Possibly Related	nausea		
Neutrophil Count Maximum Grade Possibly Related	neutrophils		
Peripheral Sensory Neuropathy Maximum Grade Possibly Related	peripheral_neuropathy		
Platelet Count Decrease Maximum Grade Possibly Related	platelets		