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-D2-Dataset.csv (Figure2)

Description: Dataset NCT01150045-D2-Dataset.csv (Figure2) is one of 4 datasets associated with PubMed ID 33821899. This dataset contains the data presented in Figure 2 of the analysis. The dataset contains one row for each patient. There is a variable for off-treatment reason for grouping patients intodifferent segments/colors of the bar chart in the figure, and a time variable for binning patients into the bar chart on the x-axis.

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.

NCT01150045-D2-Dataset.csv (Figure2) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Backbone	backbone	Celecoxib, Placebo	
Celecoxib Treatment Years (Capped at 3 years)	cele_years3		X-coordinate for grouping each bar chart segment
Grouped Off Treatment Reason	off_trt_grp	Recurrence, Adverse Events, Other, Completed Treatment	Used to group patients for separate bar chart segment at each X-coordinate