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-D1-Dataset.csv (Figure1)

Description: Dataset NCT01150045-D1-Dataset.csv (Figure1) is one of 4 datasets associated with PubMed ID 33821899. This dataset contains the data presented in the CONSORT diagram (Figure 1) from the manuscript. The dataset has one row-per-patient.

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-D1-Dataset.csv (Figure1) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Patient Registered?	registered	Yes	
Patient Withdrew prior to Randomization?	withdraw_prerando	No, Yes	
Patient Randomized?	randomized	Yes, No	
Arm Assignment	arm	FOLFOX + Celecoxib~(6 months), FOLFOX + Celecoxib~(3 months), FOLFOX + Placebo~(3 months), FOLFOX + Placebo~(6 months)	
Patient Treated as Assigned?	trt_as_assigned	Yes, No	
Patient Excluded to M1 Staging?	excluded_m1	No, Yes	
Patient Did not Receive Celecoxib/Placebo?	no_celecoxib	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Reason did not receive Celecoxib/Placebo	no_celecoxib_reason	Withdrew, Other, Adverse Events	Values will only populate when no_celecoxib = Yes
Patient Did not Receive Chemotherapy?	no_treatment	No, Yes	
Reason Did not Receive Chemotherapy	no_treatment_reason	Withdraw, Other	Values will only populate when no_treatment = Yes
Patient Discontinued Therapy?	disc_therapy	Yes, No	
Patient Discontinued Placebo Only?	disc_celecoxib	No, Yes	
Reason Discontinued Placebo Only	disc_celecoxib_reason	Disease Recurrence, Patient withdrawal, Adverse Events, Other, Death on Study, Other Complicating Disease, Physician decision, Lost to Follow-up	Values will only populate when disc_celecoxib = Yes
Patient Discontinued Chemotherapy Only?	disc_folfox	No, Yes	
Reason Discontinued Chemotherapy Only	disc_folfox_reason	Adverse Event, Physician Decision	Values will only populate when disc_folfox = Yes
Patient Discontinued Both Therapies?	disc_both	Yes, No	

LABEL	NAME	ELEMENTS	COMMENTS
Reason Discontinued Both Therapies	disc_both_reason	Patient withdrawal, Adverse Events, Other, Disease Recurrence, Other Complicating Disease, Physician decision, Death on Study	Values will only populate when disc_both = Yes
Patient Included in Primary Analysis?	primary_analysis	Yes, No	