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-D3-Dataset.csv (Table1)

Description: Dataset NCT01150045-D3-Dataset.csv (Table1) is one of 4 datasets associated with PubMed ID 33821899. This dataset contains the data presented in the baseline characteristics table (Table 1), the Kaplan-Meier figures (Figure 3a/b), the Patient Outcome analysis, determine the patients that experienced at least one grade 1 or greater adverse event possibly related to treatment, and the Treatment Adherence analysis.

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-D3-Dataset.csv (Table1) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	patid		
Backbone	backbone	Celecoxib, Placebo	
Number of FOLFOX cycles	n_cycles		Values will be missing when patient is not treated with chemotherapy
Celecoxib Treatment Years	cele_years		Values will be missing when patient is not treated with neither FOLFOX chemotherapy nor Celecoxib/ Placebo

LABEL	NAME	ELEMENTS	COMMENTS
T-stage	tstage	T1/2, T3, T4	Missing values are Unknown
N-stage	nstage_cal	N1, N2	
Aspirin use	aspirin	No, Yes	
BMI	bmi		Units are kg/m^2
Sex	sex	Female, Male	
Ethnicity	ethnicity	Not Hispanic or Latino, Hispanic or Latino	
Race	race	White, All others or not reported, Asian, Black or African American	
Age	age		Age in years
Performance Status	ps	1 to 2, 0	ECOG version
Sidedness	sidedness	Right-sided, Left-sided, Multiple	
At least 1 grade 1 AE possibly related to treatment?	gd1_rel	No, Yes	
Overall Survival Time (Months)	os_time		Time from randomization
Overall SurvivalStatus	os_stat	0=Censor, 1=Event	
Disease-free Survival Status	dfs_stat	0=Censor, 1=Event	
Disease-free Survival Time (Months)	dfs_time		Time from randomization
FOLFOX Treatment Duration (Months)	folfox_duration		Time from first treatment
Recurrence Prior to Ending Celecoxib/Placebo?	recur_prior_end_celecoxib	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Celecoxib/Placebo Treatment Adherence?	celecoxib_adherence	No, Yes	Will be missing for patients not treated with neither FOLFOX chemotherapy nor Celecoxib/ Placebo
Off-treatment Reason	derived_off_tx_rsn	Patient withdrawal after beginning treatment, Treatment completed per protocol criteria, Disease Progression during Treatment, Patient withdrawal prior to beginning treatment, Adverse Events/Side Effects, Other, Death on Study, Other Complicating Disease, Physician decision/Patient non-compliance, Lost to follow up, Patient moved, New primary cancer, Alternative Therapy	Missing values are currently unknown at time of data freeze or patients still on treatment