

C9581

Phase III Randomized Study of Adjuvant Immunotherapy With Monoclonal Antibody 17-1A Versus No Adjuvant Therapy Following Resection for State II (Modified Astler-Coller B2) Adenocarcinoma of the Colon

ClinicalTrials.gov Identifier: NCT00002968

Study Background

Trial Description

Randomized phase III trial to compare the effectiveness of surgery with or without monoclonal antibody therapy in treating patients who have stage II colon cancer. Monoclonal antibodies such as edrecolomab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. It is not yet known whether surgery to remove colon cancer is more effective with or without monoclonal antibody therapy.

Arms:

Arm I (edrecolomab): (Experimental): Patients receive adjuvant edrecolomab IV over 2 hours on day 1. Treatment repeats every 28 days for 5 courses. Patients must begin therapy no earlier than 7 days and no later than 42 days postsurgical resection. Patients also undergo observation at 3 and 6 months postrandomization.

Arm II (no treatment): (No Intervention): Patients undergo observation at 3 and 6 months postrandomization.

Objectives:

PRIMARY OBJECTIVES:

- I. To determine whether adjuvant treatment with MoAb 17-1A will improve the probability of overall and disease-free survival, and increase disease-free intervals in patients who have undergone resection of a Stage II colon cancer.
- II. To determine whether alterations in the expression of cell cycle related genes (thymidylate synthase, p53, and the cyclin-dependent kinase inhibitors p21 and p27) predict the risk of survival and recurrence in this patient population.
- III. To determine whether alterations in markers of metastatic potential-expression of DCC and measures of tumor angiogenesis (microvascular density and vascular endothelial growth factor expression)-predict the risk of survival and recurrence in this patient population.

IV. To determine whether a marker of cellular differentiation-sucrase isomaltase-predicts the risk of survival and recurrence in this patient population.

V. To determine whether DNA ploidy and cell proliferation are prognostic of tumor recurrence and overall survival in Stage II colon cancer.

VI. To determine whether interactions among these tumor markers identify subsets of patients with significantly altered outcome.

VII. To determine whether pathologic features including tumor grade; tumor mitotic (proliferation) index; tumor border configuration; host lymphoid response to tumor; and lymphatic vessel, venous vessel and perineural invasion predict outcome in this patient population.

Publication Information:

Analysis Type: Primary

PubMed ID: 21747085

Citation: [J Clin Oncol](#). 2011 Aug 10;29(23):3146-52. doi: 10.1200/JCO.2010.32.5357.
Epub 2011 Jul 11.

Associated Datasets:

NCT00002968-D1-Dataset.csv (adverse_event_exp)

NCT00002968-D2-Dataset.csv (new_primary_exp)

NCT00002968-D3-Dataset.csv (off_trt_exp)

NCT00002968-D4-Dataset.csv (onstudy_exp)

NCT00002968-D5-Dataset.csv (outcome_other_baseline_data_exp)

NCT00002968-D6-Dataset.csv (adverse_event_control)

NCT00002968-D7-Dataset.csv (new_primary_control)

NCT00002968-D8-Dataset.csv (off_trt_control)

NCT00002968-D9-Dataset.csv (onstudy_control)

NCT00002968-D10-Dataset.csv (outcome_other_baseline_data_control)

Dataset Information:

Dataset Name: NCT00002968-D5-Dataset.csv (outcome_other_baseline_data_exp)

Description: Dataset NCT00002968-D5-Dataset.csv (outcome_other_baseline_data_exp) is one of 10 datasets associated with PubMed ID 21747085. This dataset contains additional patient-level information and time-to-event analysis data of patients on the experimental arm.

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.

NCT00002968-D5-Dataset (outcome other baseline data exp) Data Dictionary:

Variable Name	Values	Variable Label	Comments
patid		De-identified Patient ID	
treatment		Experimental Treatment Arm	
age_trunc85		Age (truncated at age 85 for ages 85+)	
male	1=male, 0 = female	Gender	
stvar1	0=poorly, 1=moderately well, 2= well	Degree of Differentiation (Stratification Variable)	
racewhite	1=white, 0 = non-white	Race (white vs. non-white)	
stvar2	0=no, 1 = yes	Vascular or Lymphatic Invasion (Stratification Variable)	
stvar3	0: <5 ng, 1: >=5 ng, 2: not applicable	Preoperative Serum CEA (Stratification Variable)	
location	0 = Proximal, 1 = Distal	Tumor Location (distal vs. proximal)	
ostimeyrs	years = days/365.25	Overall survival (in years) (time from registration to death due to any cause)	
vital_status	0=alive, 1=death	Overall survival censoring variable	
dfstimeyrs	years = days/365.25	Disease-Free Survival (in years) (time from registration to first of either recurrence of primary disease or death from any cause)	
dfscens	0= no event, 1 = event	Disease-free censoring variable	
RACE_ID	African American, American Indian or Alaska Native, Asian, Hispanic	Race	

	American, Indian Subcontinent, Other, Unknown, White		
notcorrrend	1=not concurrently randomized	Not concurrently randomized	
deaddis	0= no event, 1 = event	Disease-specific OS	
rficens2	0= no event, 1 = event	Disease-specific DFS	
cause	2=disease related, 3=other	Cause of Death	