CALGB-80101

Phase III Intergroup Trial of Adjuvant Chemoradiation After Resection of Gastric or Gastroesophageal Adenocarcinoma

ClinicalTrial.gov Identifier: NCT00052910

Study Background

Trial Description

RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Combining chemotherapy with radiation therapy after surgery may kill any remaining tumor cells following surgery. It is not yet known which chemotherapy and radiation therapy regimen is more effective in treating stomach or esophageal cancer. PURPOSE: Randomized phase III trial to compare two different chemotherapy and radiation therapy regimens in treating patients who have undergone surgery for stomach or esophageal cancer.

Arms:

Arm I: (Active Comparator): Patients receive leucovorin calcium IV and fluorouracil (5-FU) IV on days 1-5 of courses 1, 3, and 4. Courses repeat every 28 days. During course 2, patients undergo radiotherapy 5 days a week and receive 5-FU IV continuously for 5 to 6 weeks. Patients rest for 28-35 days between course 2 and 3.

Arm II: (Experimental): Patients receive epirubicin IV over 3-15 minutes and cisplatin IV over 1 hour on day 1 and 5-FU IV continuously on days 1-21 during course 1. Beginning 1 week later, patients undergo radiotherapy 5 days a week and 5-FU IV continuously for 5 weeks. Patients rest for 28-35 days before beginning course 2 of chemotherapy. Patients then receive epirubicin, cisplatin, and 5-FU as in course 1. Treatment repeats every 21 days for 2 courses.

Objectives:

OBJECTIVES:

- Compare overall survival in patients with resected gastric adenocarcinoma treated with epirubicin, cisplatin, and infusional fluorouracil (5-FU) vs 5-FU bolus and leucovorin calcium before and after 5-FU plus radiotherapy.

- Compare disease-free survival and local and distant recurrence rates in these patients treated with these regimens.

- Correlate the expression of putative prognostic markers (including TS, ERCC-1, MSI, E-cadherin, EGFR, p27, COX-2, and c-erbB-2) with overall survival of patients treated with these regimens.

- Correlate specific germline polymorphisms related to chemotherapy metabolism and resistance (including UGT2B7 [epirubicin], GST [cisplatin], ERCCI [cisplatin], XRCC1 [cisplatin], TS [5-FU], DPD [5-FU], and EGFR polymorphisms) with treatment-related toxicity and overall survival of these patients.

- Correlate serum levels of insulin-like growth factor-1 (IGF-1), IGF-2, and IGF-binding protein 3 with overall survival of patients treated with these regimens.

OUTLINE: This is a randomized, multicenter study. Patients are stratified according to depth of tumor penetration (T1 or T2 vs T3 vs T4), lymph node involvement (0 vs 1-3 vs >=4), and extent of lymphadenectomy (D1 or D2 vs D0 or unknown). Patients are randomized to 1 of 2 treatment arms.

Publication Information:

Analysis Type: Primary

Pubmed ID: 28976791

Citation: J Clin Oncol. 2017 Nov 10;35(32):3671-3677. doi: 10.1200/JCO.2017.74.2130. Epub 2017 Oct 4.

Associated Datasets: NCT00052910-D1-Dataset (ae), NCT00052910-D2-Dataset (efficacy)

Dataset Information:

Dataset Name: NCT00052910-D1-Dataset.csv (ae)

Description: Dataset NCT00052910-D1-Dataset.csv (ae) is one of 2 datasets associated with PubMed ID 28976791. This dataset contains information that will allow you to reproduce adverse events reported in the manuscript.

NCT00052910-D1-Dataset.csv (ae) Data Dictionary:

LABEL	NAME	Elements	comments
PATIENT_ID	patid		
MEDDRA CODE	MEDDRA_CODE		Missing=No events reported
CTC Version	CTC_VERSION	2, 3	Which CTC Version was used to collect the adverse events? Missing=No events reported
GRADE_ID	GRADE_ID	1, 2, 3, 4, 5,	Missing=No events reported
RELATION_ID	RELATION_ID	3 (possibly related), 4 (probably related), 5 (definitely related)	Missing=No events reported
Name of Adverse Event reported	EventName		Meddra Term associated with each MEDDRA_CODE Missing=No events reported
Category or Body System of Event	EventCat	Allergy/Immunology, Appendix Iv Rtog/Eortc Late Radiation Morbidity Scoring Scheme (Use For Adverse Events Occurring Greater Than 90 Days After Radiation	Missing values indicate the patient did not report any adverse events

		Therapy.), Auditory/Ear, Blood/Bone Marrow, Cardiac Arrhythmia, Cardiac General, Cardiovascular (General), Coagulation, Constitutional Symptoms, Death, Dermatology/Skin, Endocrine, Gastrointestinal, Hemorrhage/Bleeding, Hepatobiliary/Pancreas, Infection, Lymphatics, Metabolic/Laboratory, Musculoskeletal/Soft Tissue, Neurology, Ocular/Visual, Pain, Pulmonary/Upper Respiratory, Renal/Genitourinary, Sexual/Reproductive Function, Surgery/Intra-Operative Injury, Syndromes, Vascular,	