

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-D2-Dataset.csv (efficacy)

Description: Dataset NCT00052910-D2-Dataset.csv (efficacy) is one of 2 datasets associated with PubMed ID 28976791. This dataset contains information that will allow you to reproduce the baseline characteristics table and primary analysis.

NCT00052910-D2-Dataset.csv (efficacy) Data Dictionary:

LABEL	NAME	elements	Comments
PATIENT_ID	patid		
ECOG Performance status	PERFORMANCE_ID	0-2	
Had any prior cancer?	Hx_oth_cancer	1='No' 2='Yes'	Missing=unknown or not reported
Stable weight prior to entry on study	stable_weigh	1='No' 2='Yes'	Missing=unknown or not reported
Patient examined by radiation oncologist?	examed_by_radiati on_oncologist	0='No' 1='Yes'	Missing=unknown or not reported
Presence of bilateral renal function?	bilateral_renal_func tion	0='No' 1='Yes'	Missing=unknown or not reported
No myocardial infarction in the past 6 months, or other significant heart disease?	No_cardiact_conditi on	0='No' 1='Yes'	Missing=unknown or not reported
Prior chemotherapy?	prior_chemo	0='No' 1='Yes'	Missing=unknown or not reported
Prior radiation?	prior_radiation	0='No' 1='Yes'	Missing=unknown or not reported
Primary site of GE Junction	Gastro_esophageal_ junction	0='No' 1='Yes'	Missing=unknown or not reported. All patients reported "GE" as their prim_site.

Primary site Cardia	cardia	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Proximal gastr"
Primary site Fundus	fundus	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Proximal gastr"
Primary site Body	body_corpus	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Distal gastric"
Primary site Antrum	antrum	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Distal gastric"
Primary site Pylorus	pylorus_pyloric_ch annel	0='No' 1='Yes';	Missing=unknown or not reported. For patients that reported a prim_site of "Distal gastric"
Primary site Greater Curv	greater_curvature	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Distal gastric"
Primary site Lesser Curv	lesser_curvature	0='No' 1='Yes'	Missing=unknown or not reported. For patients that reported a prim_site of "Distal

			gastric"
Primary site Stomach NOS	stomach_NOS	0='No' 1='Yes'	Missing=unknown or not reported
Histologic grade	Histologic_grade	1='Well differentiated (grade I)' 2='Moderately well differentiated (grade II)' 3='Poorly differentiated (grade III)' 4='Undifferentiated (grade IV)'	Missing=unknown or not reported
Number of lymph nodes examined	num_lymph_node_examined		Missing=unknown or not reported
Number of positive lymph nodes	num_pos_lymph_node		Missing=unknown or not reported
T stage	T_stage	1='T1' 2='T2' 3='T3' 4='T4'	Missing=unknown or not reported
N stage	N_stage	0='N0' 1='N1' 2='N2' 3='N3'	Missing=unknown or not reported
M stage	M_stage	0='M0' 1='M1'	Missing=unknown or not reported
If patient has T2N0M0, does tumor extend beyond muscularis propria?	T2N0M0_spec	1='No' 2='Yes'	Missing=unknown or not reported
Location of progression	PD_location	1='Local/regional' 2='Distant'	Missing=unknown or not reported
Ethnicity	ETHNIC_ID	1='Hispanic' 2='Non-hispanic' 9='Unknown'	
Gender	SEX_ID	1='Male' 2='Female'	

Race	RACE_ID	1='White' 3='Black' 4='Asian' 9 = 'Other'	
Arm	TREAT_ASSIGNED	1='Arm A: 5FU/LV + Radiation' 2='Arm B: ECF + Radiation'	"Arm A" is synonymous with "Arm I" in the ClinicalTrials.gov record and "Arm B" is synonymous with "Arm II"
Stratum	STRATUM_GRP_ID	1='T1 or T2, 0 nodes, D1 or D2' 2='T1 or T2, 0 nodes, D0 or Unknown' 3='T1 or T2, 1-3 nodes, D1 or D2' 4='T1 or T2, 1-3 nodes, D0 or Unknown' 5='T1 or T2, >=4 nodes, D1 or D2' 6='T1 or T2, >=4 nodes, D0 or Unknown' 7='T3, 0 nodes, D1 or D2' 8='T3, 0 nodes, D0 or Unknown' 9='T3, 1-3 nodes, D1 or D2' 10='T3, 1-3 nodes, D0 or Unknown' 11='T3, >=4 nodes, D1 or D2' 12='T3, >=4 nodes, D0 or Unknown' 13='T4, 0 nodes, D1 or D2' 14='T4, 0 nodes, D0 or Unknown' 15='T4, 1-3 nodes, D1 or D2' 16='T4, 1-3 nodes, D0	

		or Unknown' 17='T4, >=4 nodes, D1 or D2' 18='T4, >=4 nodes, D0 or Unknown'	
Death	death_final	1='Dead' 0='Alive'	
Time from registration to event for overall survival (in years)	os_year		
Status indicator for disease free survival	DFS_status	1='Event' 0='Censored'	
Time from registration to event for disease-free survival (in years)	DFS_year		
Off treatment reason	offtrt_reason	1='Completed TX' 2='PD' 3='Adverse event' 4='Death' 5='w/d after beginning TX' 6='w/d before beginning TX' 7='Alternative tx' 8='Other disease' 11='Other'	Missing='No TX Info Submitted'
Age (at registration) categories	agecat	1 = <60 yrs 2 = >=60 yrs	
Age (years)	age	continuous	
Primary tumor location	prim_site	Distal gastric, GE, Multicentric, Proximal gastr, Stomach NOS,	Missing=Unknown