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Phase III, Randomized, Study of Sulfasalazine Versus Placebo in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy

ClinicalTrial.gov Identifier: NCT01198145

Study Background

Trial Description

RATIONALE: Sulfasalazine may relieve diarrhea in patients with cancer who are undergoing pelvic radiation therapy. PURPOSE: This randomized phase III trial is studying sulfasalazine to see how well it works in preventing acute diarrhea in patients with cancer who are undergoing pelvic radiation therapy.

Arms:

Arm I: Sulfasalazine: (Experimental): Patients receive oral sulfasalazine twice daily during radiotherapy and for 4 weeks after completion of radiotherapy.

Arm II: Placebo: (Placebo Comparator): Patients receive oral placebo twice daily during radiotherapy and for 4 weeks after completion of radiotherapy.

Objectives:

Primary

- To determine whether sulfasalazine is effective in reducing the acute treatment-related diarrhea in patients receiving pelvic radiotherapy as measured by NCI CTC v4.0 in patients receiving pelvic external-beam radiotherapy as adjuvant or primary treatment for malignancy.

Secondary

- To determine whether sulfasalazine can reduce chronic treatment-related bowel dysfunction following completion of therapy.

- To determine whether sulfasalazine causes any toxicity in this situation.

Tertiary

- To bank blood products for future studies, as part of ongoing research for NCCTG studies (Mayo Clinic Rochester only). (Translational)

OUTLINE: This is a multicenter study. Patients are stratified according to history of anterior resection of the rectum (yes vs no); total planned cumulative dosing, including boost fields of

external-beam radiotherapy (4500-5350 cGy vs > 5350 cGy); and concurrent radiosensitizing fluorouracil, capecitabine, or oxaliplatin (yes vs no). Patients are randomized to 1 of 2 treatment arms.

Publication Information:

Analysis Type: Primary

Pubmed ID: 27354129

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Associated Datasets: NCT01198145-D1 (analysis), NCT01198145-D2 (supplemental)

Dataset Information:

Dataset Name: NCT01198145-D2 (supplemental)

Description: Dataset NCT01198145-D2 (supplemental) is one of 2 datasets associated with PubMed ID 27354129. This dataset contains information that will allow you to reproduce supplemental table 1. All Adverse events reported were collected and graded using Common Terminology Criteria for Adverse Events (CTCAE) v4.0.

NCT01198145-D2 (supplemental) Data Dictionary:

LABEL	NAME	elements	comments
Patient reference	PATREF		De-identified patient reference
Treatment Arm	ARM	A= Placebo B= Sulfasalazine	
Toxicity	TOXICITY	Literal values of event	Collected and graded using Common Terminology Criteria for Adverse Events (CTCAE) v4.0.
Grade	GRADE	0, 1, 2, 3, 4	Graded using Common Terminology Criteria for Adverse Events (CTCAE) v4.0. Missing grades indicate the patient was not assessed for the event during the cycle.
Cycle	CYCLE		Cycle number during which the event occurred.