N08C9

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

Citation: Int J Radiat Oncol Biol Phys. 2016 Jul 15;95(4):1168-74. doi: 10.1016/j.ijrobp.2016.01.063. Epub 2016 Apr 23.

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

Dataset Information:

Dataset Name: NCT01198145-D1 (analysis)

Description: Dataset NCT01198145-D1 (analysis) is one of 2 datasets associated with PubMed ID 27354129. This dataset contains information that will allow you to reproduce the entire manuscript, except Supplemental Table 1 which is included in a separate dataset. All Adverse events reported were collected and graded using Common Terminology Criteria for Adverse Events (CTCAE) v4.0.

NCT01198145-D1 (analysis) Data Dictionary:

LABEL	NAME	elements	comments
Patient reference	PATREF		De-identified patient reference
Treatment Arm	ARM	A= Placebo B= Sulfasalazine	
Age (in years)	AGE	Continuous	
Race	RACE1	White, Black or African American, American Indian or Alaska Native, Asian, Unknown: Patient unsure	
Sex	SEX	Male, Female	
History of rectum resection	rectum_ resection	Yes No	
Total cumulative dose	total_cumulative_dose	>5350 cGy, 4500-5350 cGy	
Concurrent chemotherapy	concurrent_chemo	Yes, No	
Tumor type	tumor_type	Colon/Recta Anal margin Endometrial Prostate Pelvic Vaginal Vau Ovarian Uterus	

		Infiltratin	
Maximum grade diarrhea	Max_diarrhea	4, 1, 3, 0, 2	
Maximum grade tenesmus after Radiotherapy	Max_tenesmus_postRT	Missing=Not collected, 1, 0, 2	
Maximum grade abdominal pain after Radiotherapy	Max_abpain_postRT	Missing=Not collected, 1, 0, 2	
Maximum grade constipation after Radiotherapy	Max_constipation_postRT	Missing=Not collected, 1, 0, 2	
Maximum grade rectal bleeding after Radiotherapy	Max_rectalbleeding_postRT	Missing=Not collected, 1, 0, 2	
Maximum grade diarrhea after Radiotherapy	Max_diarrhea_postRT	Missing=Not collected, 1, 0, 2, 3	
Maximum grade tenesmus during Radiotherapy	Max_tenesmus_RT	0, 2, 1, 3	
Maximum grade abdominal pain during Radiotherapy	Max_abpain_RT	1, 0, 3, 2	
Maximum grade constipation during Radiotherapy	Max_constipation_RT	2, 1, 0	
Maximum grade rectal bleeding during Radiotherapy	Max_rectalbleeding_RT	1, 0	
Maximum grade	Max_diarrhea_RT	4, 1, 3, 0, 2	

diarrhea during Radiotherapy			
End of active treatment reason	ENDATRSN	Refused Further Treatment, Completed Study Per Protocol, Other, Adverse Event	Used to produce Supplemental Table 2.