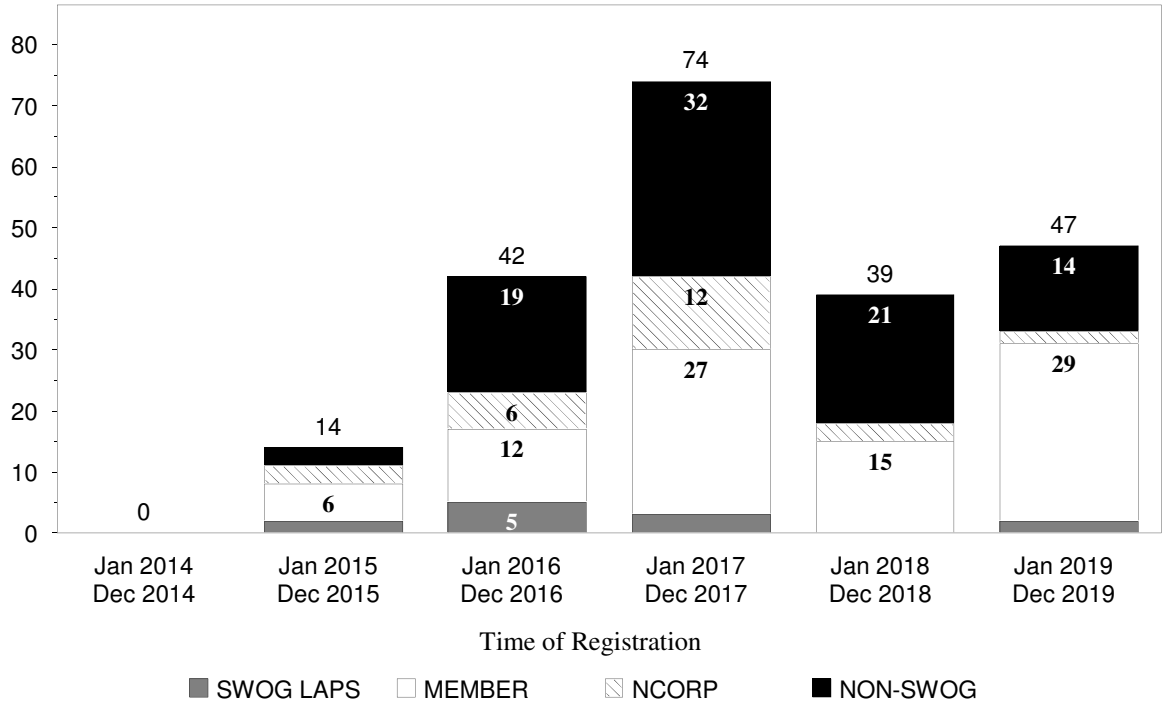
PALLIATIVE AND END OF LIFE CARE COMMITTEE

CONTENTS

Patient Registrations to Studies

by 12 Month Intervals
PALLIATIVE AND END OF LIFE CARE COMMITTEE



Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

PALLIATIVE AND END OF LIFE CARE COMMITTEE

	Jul 2019 Dec 2019	Jan 2019 Jun 2019	Jul 2018 Dec 2018	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Randomization Surgery	7	12	2	26
Randomization Non-surgical M	10	7	3	25
Patient Choice Surgery	0	11	9	65
Patient Choice Non-surgical M	0	0	0	100
	17	30	14	216

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

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Participants:
SWOG, CTSU (Supported by Alliance)

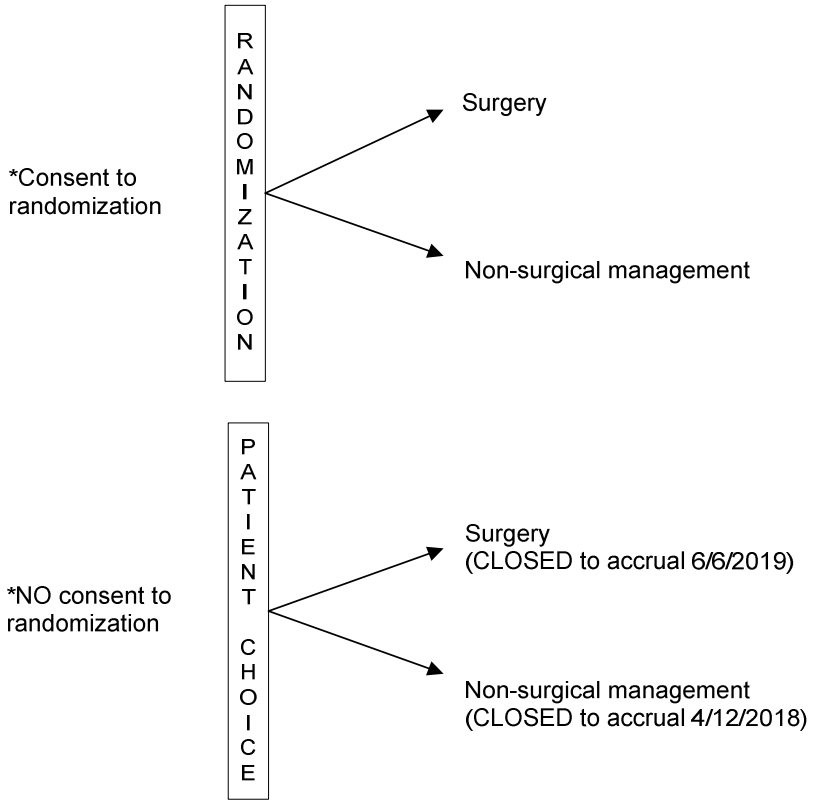
Date Activated:
03/09/2015

Study Chairs:
R Krouse, J Deneve, A Secord (Alliance)

Statisticians:
G Anderson, K Arnold

Data Coordinator:
R Topacio

SCHEMA



*Patients will be enrolled into either the randomized or patient choice portion, not both

Objectives

To compare quality of life, as assessed by the number of days alive and residing outside of the hospital within the first 91 days (13 weeks) after registration, among patients with malignant bowel obstruction (MBO) who receive surgical intervention and similar patients treated non-surgically.

To explore whether there are differences in other health related quality of life (HRQOL) factors of particular interest in this population, including ability to eat, days with nasogastric tube, development of nausea, days of intravenous hydration, days eating solid foods and days drinking that are different for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

To explore whether overall survival is different for patients with MBO who receive surgical intervention as compared to non-surgical intervention. To estimate the effects of surgical versus non-surgical management on quality of life after adjustment for non-adherence to initially assigned/chosen treatment.

To explore whether there are clinical factors (e.g., ascites, albumin, carcinomatosis) that predict better quality of life outcomes for patients with MBO who receive surgical intervention as compared to non-surgical intervention.

Patient Population

Patients must have clinical evidence of a small bowel obstruction (via history, physical, and radiographic examination) distal to ligament of Treitz, with radiographic confirmation prior to registration. Patients must have intra-abdominal primary cancer with incurable disease. Patients may still have primary tumor as long as it is not a primary large bowel obstruction from colorectal cancer. Patients must not have signs of bowel perforation necessitating surgery or "acute" abdomen as evidenced by peritonitis on physical exam within two days prior to registration.

Patients must be registered to the study within three days after being seen by a surgical team for MBO or within three days after completion of indicated treatment (e.g. TPN, anticoagulation reversal) to make them eligible for surgical intervention, whichever is later, and prior to any treatment (surgical or non-surgical) for MBO. Somatostatin analogues may be used prior to registration if that use is limited to not more than the two days just prior to registration.

Patients must be able to tolerate a major surgical procedure based on clinical evaluation, status of their cancer, and any other underlying medical problems. A member of the patient's surgical team must indicate equipoise for the benefit of the surgical treatment for MBO. Patients must be 18 years or older and have Zubrod performance status of 0-2 within seven days prior to hospitalization. Serum albumin must be planned to be collected after hospital admission, but prior to treatment. History and physical must be obtained within three days prior to registration. Patients must be able to complete the study questionnaires in English or Spanish.

Stratification/Descriptive Factors

Patient randomization will be stratified by primary tumor type: colorectal cancer vs ovarian cancer vs other cancer.

Accrual Goals

A total of 220 patients will be accrued to achieve 200 eligible patients, with a target of 50 eligible patients in the randomized component.

Summary Statement

This study was activated on March 9, 2015, at limited institutions. The Patient Choice arms are permanently closed. As of December 31, 2019, 216 patients have been registered at 30 institutions, including 51 patients to the randomized portion. The Latin American sites in Mexico, Peru, and Colombia have randomized 16 patients.

One randomized patient is ineligible due to receiving non-surgical treatment prior to randomization. Three patients registered to the Patient Choice Surgery arm are ineligible, two due to surgery prior to registration and one who was registered more than 14 days after confirmation of MBO. Two patients registered to the Patient Choice Non-surgical Management arm are ineligible, one due to non-intra-abdominal primary cancer and one whose bowel obstruction was not past the ligament of Treitz. Among 160 eligible patients in the Patient Choice group, 62 (39%) chose surgery at time of consent.

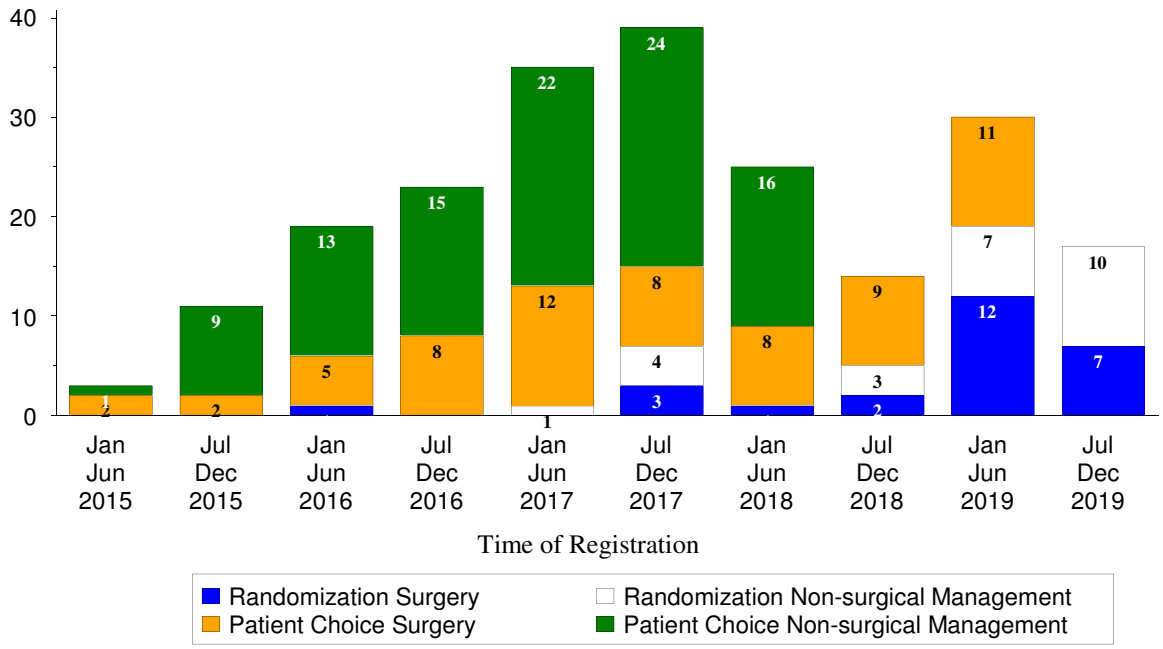
Ten randomized patients had a major protocol deviation due to not receiving assigned treatment. One patient on the Patient Choice Surgery arm had a major protocol deviation due to not having surgery. Twelve patients on the Patient Choice Non-surgical Management arm had major protocol deviations due to receiving surgery.

Eleven patients are actively being followed and completing study questionnaires and dietary recalls. Seventeen patients who are off treatment for various reasons have withdrawn consent for any further follow-up.

Toxicities are reported in groups according to treatment specified at registration, regardless of randomization status: surgery vs non-surgical management. Among 83 patients registered to the Surgery arms who have had adverse events assessed, one patient experienced Grade 4 anemia and one patient experienced Grade 4 myocardial infarction. Among 112 patients who have had adverse events assessed on the Non-surgical Management arms, one patient had Grade 5 sepsis, pneumonitis and cardiac arrest, and one patient experienced Grade 4 anemia and post-operative hemorrhage during a second hospitalization.

Initial Registrations by 6 Month Intervals

Divisions by ARM



Registration by Network Groups

Registrations ending December 31, 2019

Institutions	Total Reg
SWOG	127
NRG	61
ALLIANCE	26
ECOG-ACRIN	2
Total (4 Network Groups)	**216**

Registration by Institution

Registrations ending December 31, 2019

Institutions	Total Reg
The West Clinic - Wolf River (TN089)	42
Long Island Jewish Medical Center (NY065)	20
Banner University Medical Center - Tucson (AZ017)	18
North Shore University Hospital (NY064)	18
University of Kansas Cancer Center (KS004)	18
University of Oklahoma Health Sciences Center (OK003)	13
Duke University Medical Center (NC010)	11
City of Hope Comprehensive Cancer Center (CA043)	9
Instituto Nacional De Cancerologia de Mexico (48007)	8
University of Michigan Comprehensive Cancer Cen (MI014)	8
Instituto Nacional de Enfermedades Neoplasicas (55004)	7
University of Arkansas for Medical Sciences (AR006)	6
Medical University of South Carolina (SC008)	5
Medical College of Wisconsin (WI013)	4
Rhode Island Hospital (RI005)	4
Valley Health / Winchester Medical Center (VA008)	4
Moffitt Cancer Center (FL065)	3
University Hospital (TX182)	3
Baylor University Medical Center (TX012)	2
M D Anderson Cancer Center (TX035)	2
UMass Memorial Medical Center - University Camp (MA011)	2
Baylor College of Medicine/Dan L Duncan Compreh (TX041)	1
Essentia Health Cancer Center (MN024)	1
Instituto Nacional De Cancerologia (15002)	1
Loma Linda University Medical Center (CA078)	1
NYP/Columbia University Medical Center/Herbert (NY024)	1
Rush University Medical Center (IL043)	1
Southside Hospital (NY394)	1
University of New Mexico Cancer Center (NM004)	1
University of Tennessee Health Science Center (TN030)	1
Total (30 Institutions)	**216**

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2019; Data as of January 30, 2020

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER REGISTERED	216	26	25	65	100
INELIGIBLE	6	1	0	3	2
ELIGIBLE	210	25	25	62	98
Analyzable, Pend. Elig.	10	8	2	0	0
ADVERSE EVENT ASSESSMENT					
Evaluable	204	22	25	61	96
Too Early	6	3	0	1	2

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending December 31, 2019; Data as of January 30, 2020

	Randomization Surgery (n=25)		Randomization Non-surgical Management (n=25)		Patient Choice Surgery (n=62)		Patient Choice Non-surgical Management (n=98)	
AGE								
Median	63.8		61.2		61.0		59.3	
Minimum	43.2		45.7		23.0		32.7	
Maximum	91.1		82.3		90.8		85.6	
SEX								
Males	8	32%	10	40%	25	40%	31	32%
Females	17	68%	15	60%	37	60%	67	68%
HISPANIC								
Yes	8	32%	6	24%	6	10%	14	14%
No	14	56%	17	68%	55	89%	82	84%
Unknown	3	12%	2	8%	1	2%	2	2%
RACE								
White	10	40%	11	44%	42	68%	72	73%
Black	6	24%	7	28%	14	23%	16	16%
Asian	0	0%	1	4%	1	2%	2	2%
Pacific Islander	0	0%	0	0%	0	0%	2	2%
Native American	1	4%	1	4%	0	0%	1	1%
Unknown	8	32%	5	20%	5	8%	5	5%
PRIMARY TUMOR TYPE								
Colorectal cancer	8	32%	9	36%	21	34%	26	27%
Ovarian cancer	9	36%	7	28%	11	18%	35	36%
Other cancer	8	32%	9	36%	30	48%	37	38%

Treatment Summary

All eligible and selected ineligible patients included

Registrations ending December 31, 2019; Data as of January 30, 2020

	TOTAL	Randomized	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	11	4	7	0
NUMBER OFF PROTOCOL TREATMENT	199	46	55	98
REASON OFF TREATMENT				
Treatment completed as planned	27	2	14	11
Adverse Event or side effects	0	0	0	0
Refusal unrelated to adverse event	27	3	6	18
Progression/relapse	15	2	4	9
Death	128	37	31	60
Other - not protocol specified	0	0	0	0
Reason under review	2	2	0	0
MAJOR PROTOCOL DEVIATIONS	23	10	1	12
LOST TO FOLLOW-UP	0	0	0	0
CONSENT WITHDRAWAL AFTER TREATMENT INITIATION	17	3	3	11

Number of Patients with a Given Type and Grade of Adverse Event

Classified by Study Arm

Adverse Events Unlikely or Not Related to Treatment Excluded

All Eligible and Selected Ineligible Patients Included

Registrations ending December 31, 2019; Data as of January 30, 2020

	Surgery Arms (n=83) Grade						Non-surgical Management Arms (n=121) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal infection	81	0	0	2	0	0	120	0	0	1	0	0
Abdominal pain	83	0	0	0	0	0	120	0	0	1	0	0
Anemia	74	1	1	6	1	0	116	0	2	2	1	0
Aspiration	82	0	1	0	0	0	120	0	1	0	0	0
Cardiac arrest	83	0	0	0	0	0	120	0	0	0	0	1
Diarrhea	83	0	0	0	0	0	120	0	1	0	0	0
Esophageal ulcer	83	0	0	0	0	0	120	1	0	0	0	0
Fever	82	1	0	0	0	0	120	0	1	0	0	0
GI disorders-Other, specify	82	0	1	0	0	0	121	0	0	0	0	0
Gastric ulcer	83	0	0	0	0	0	120	1	0	0	0	0
Gastrointestinal fistula	78	0	2	3	0	0	121	0	0	0	0	0
Gastrointestinal pain	82	0	0	1	0	0	118	1	0	2	0	0
Hypoalbuminemia	83	0	0	0	0	0	120	0	0	1	0	0
Ileus	82	0	0	1	0	0	120	0	0	1	0	0
Myocardial infarction	82	0	0	0	1	0	121	0	0	0	0	0
Nausea	83	0	0	0	0	0	120	0	1	0	0	0
Peritoneal infection	82	0	0	1	0	0	121	0	0	0	0	0
Pleural effusion	82	0	0	1	0	0	121	0	0	0	0	0
Pneumonitis	83	0	0	0	0	0	120	0	0	0	0	1
Postoperative hemorrhage	83	0	0	0	0	0	120	0	0	0	1	0
Sepsis	83	0	0	0	0	0	120	0	0	0	0	1
Sinus bradycardia	83	0	0	0	0	0	119	2	0	0	0	0
Urinary tract infection	81	0	1	1	0	0	121	0	0	0	0	0
Urinary tract obstruction	83	0	0	0	0	0	120	0	0	1	0	0
Vomiting	83	0	0	0	0	0	120	0	0	1	0	0
Wound complication	80	0	3	0	0	0	121	0	0	0	0	0
Wound dehiscence	81	0	2	0	0	0	120	0	1	0	0	0
Wound infection	81	0	0	2	0	0	120	0	1	0	0	0
MAX. GRADE ANY ADVERSE EVENT	67	1	2	11	2	0	108	2	3	6	1	1

S1820 Pilot

Coordinating Group: SWOG

A Randomized Trial of the Altering Intake, Managing Symptoms Intervention for Bowel Dysfunction in Rectal Cancer Survivors Compared to a Healthy Living Education Control: A Feasibility and Preliminary Efficacy Study (AIMS-RC)

Participants:
SWOG, CTSU

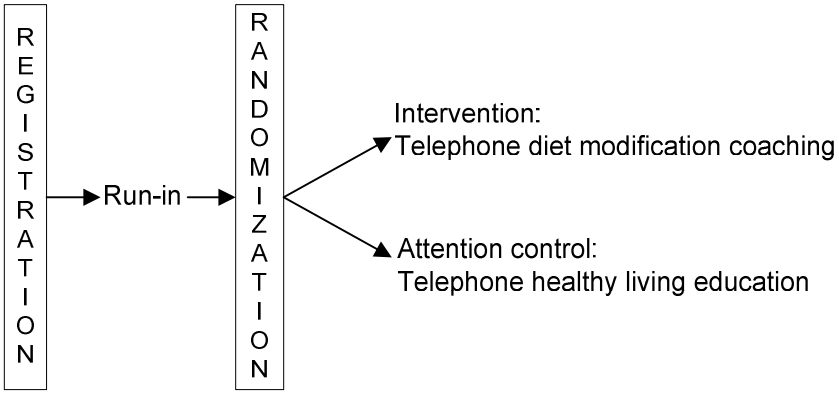
Date Activated:
12/09/2019

Study Chairs:
V Sun, C Thomson

Statisticians:
K Guthrie, K Arnold

Data Coordinator:
R Topacio

SCHEMA



Objectives

To compare total bowel function score, as measured by the Memorial Sloan-Kettering Cancer Center Bowel Function Index (BFI), at 18 weeks post-randomization between the intervention and attention control arms.

To compare total bowel function score at 26 weeks post-randomization between the intervention and attention control arms.

To compare bowel function subscale scores (dietary, urgency, frequency), as measured by the BFI at both

18 and 26 weeks post-randomization between the intervention and attention control arms.

To compare lower anterior resection syndrome (LARS) scores (for anastomosis participants only), quality of life, and dietary quality at both 18 and 26 weeks post-randomization between the intervention and attention control arms.

To compare motivation, self-efficacy, and positive/negative affect at both 18 and 26 weeks post-randomization between the intervention and attention control arms.

To assess study feasibility, adherence, retention, and acceptability at both 18 and 26 weeks post-randomization.

To explore variation in primary and secondary study outcomes according to sex, and to investigate whether intervention effects on the primary outcome differ across subgroups defined by sex.

Patient Population

Patients must have prior history of rectosigmoid colon cancer or rectal cancer. Patients must have a post-surgical permanent ostomy or anastomosis.

Patient's last date of treatment for rectal cancer (any surgery, chemotherapy, radiation therapy) must be at least 6 months prior to registration and not more than 24 months prior to registration.

Anastomosis patients must have LARS score of 21-42 (minor to major symptoms). Patients must be able to read, write and speak English. Patients must be at least 18 years of age. Patients must not be currently undergoing treatment for another cancer. Patients must not have been diagnosed with inflammatory bowel disease.

Stratification/Descriptive Factors

Patient randomization will be stratified according to the following factors: (1) sex: female vs male; and (2) ostomy status: permanent ostomy vs anastomosis.

Accrual Goals

The accrual goal is 94 randomized patients to achieve 88 eligible randomized patients, which is anticipated to require 126 patients registered to the run-in.