CANCER SURVIVORSHIP COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
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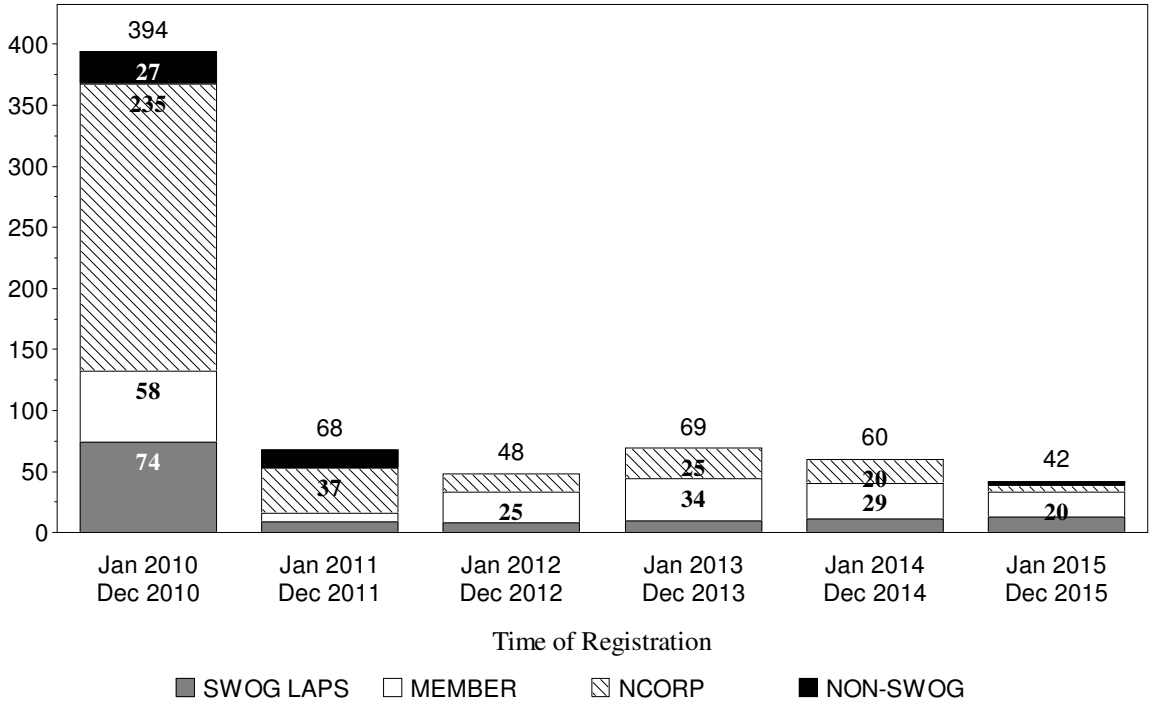

Screening registrations and registrations to Biologic only studies are excluded

Patient Registrations by Study and Arm

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	Jul 2015 Dec 2015	Jan 2015 Jun 2015	Jul 2014 Dec 2014	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Patient Choice: Surgery	2	2	0	4
Patient Choice: Non-surgical Management	9	1	0	10
	11	3	0	14
C70807 Pros, MEAL Study*				
Total Registrations	5	23	26	162

* For non-SWOG coordinated studies only SWOG registrations are shown.

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction

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Participants:
SWOG, Alliance

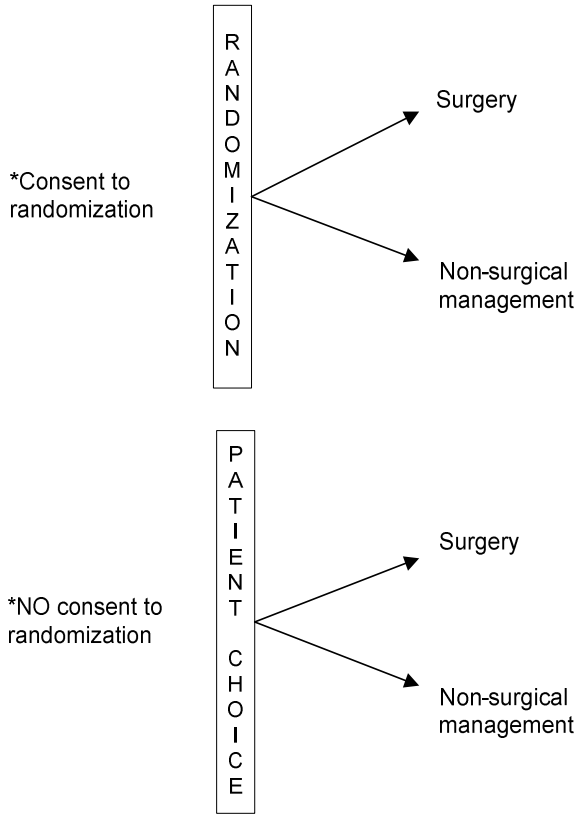
Date Activated:
03/09/2015

Study Chairs:
R Krouse, B Bagwell, 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 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 200 patients will be accrued to achieve 180 eligible patients, with a target of at least 50 eligible patients in the randomized component.

Summary Statement

This study activated on March 9, 2015, to limited institutions. As of December 31, 2015, 14 patients have been registered, all to the patient choice portion.

Nine patients are no longer on active follow-up: seven patients have died, one patient progressed, and one patient is still under review. Three patients have major protocol deviations: two patients who choose non-surgical management did not receive a somatostatin analogue, and one patient who chose non-surgical management did receive surgery. Among 14 patients who have had adverse events assessed, one patient on the non-surgical management arm reported Grade 3 abdominal distension.

Revision #5, distributed February 15, 2016, clarified eligibility language and study follow-up options.

Registration by Institution

Registrations ending December 31, 2015

Institutions	Total Reg
Alliance	3
Arizona MC, U of	3
MUSC MU-NCORP	3
Arkansas, U of	2
Michigan, U of	2
City of Hope Med Ctr	1
Total (6 Institutions)	**14**

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2015; Data as of February 26, 2016

	TOTAL	Patient Choice: Surgery	Patient Choice: Non-surgical Management
NUMBER REGISTERED	14	4	10
ELIGIBLE	14	4	10
ADVERSE EVENT ASSESSMENT			
Evaluable	14	4	10

Patient Characteristics

Registrations ending December 31, 2015; Data as of February 26, 2016

	Patient Choice: Surgery (n=4)		Patient Choice: Non-surgical Management (n=10)	
AGE				
Median	64.3		54.6	
Minimum	51.8		43.3	
Maximum	68.9		84.0	
SEX				
Males	1	25%	2	20%
Females	3	75%	8	80%
HISPANIC				
Yes	2	50%	3	30%
No	2	50%	7	70%
RACE				
White	3	75%	8	80%
Black	0	0%	2	20%
Unknown	1	25%	0	0%
PRIMARY TUMOR TYPE				
Colorectal cancer	1	25%	0	0%
Ovarian cancer	2	50%	3	30%
Other cancer	1	25%	7	70%

Treatment Summary

Registrations ending December 31, 2015; Data as of February 26, 2016

	TOTAL	Patient Choice: Surgery	Patient Choice: Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	5	2	3
NUMBER OFF PROTOCOL TREATMENT	9	2	7
REASON OFF TREATMENT			
Treatment completed as planned	0	0	0
Adverse Event or side effects	0	0	0
Refusal unrelated to adverse event	0	0	0
Progression/relapse	1	0	1
Death	7	1	6
Other - not protocol specified	0	0	0
Reason under review	1	1	0
MAJOR PROTOCOL DEVIATIONS	3	0	3

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

Adverse Events Unlikely or Not Related to Treatment Excluded

Registrations ending December 31, 2015; Data as of February 26, 2016

	Patient Choice: Surgery (n=4) Grade						Patient Choice: Non-surgical Management (n=10) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal distension	4	0	0	0	0	0	9	0	0	1	0	0
Abdominal pain	4	0	0	0	0	0	9	0	1	0	0	0
MAX. GRADE ANY ADVERSE EVENT	4	0	0	0	0	0	9	0	0	1	0	0