CANCER SURVIVORSHIP COMMITTEE

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By 12 Month Intervals
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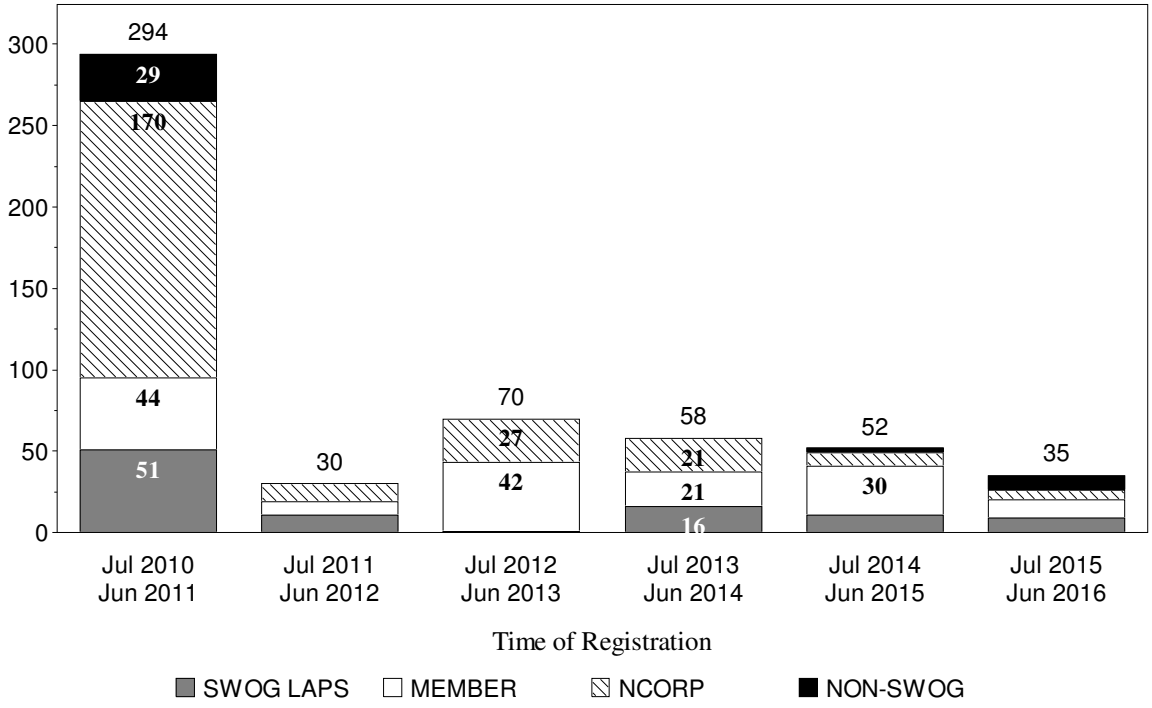

Screening registrations and registrations to Biologic only studies are excluded

Patient Registrations by Study and Arm

CANCER SURVIVORSHIP COMMITTEE

	Jan 2016 Jun 2016	Jul 2015 Dec 2015	Jan 2015 Jun 2015	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Randomization: Surgery	1	0	0	1
Patient Choice: Surgery	5	2	2	9
Patient Choice: Non-surgical Management	13	9	1	23
	19	11	3	33
C70807 Pros, MEAL Study*				
Total Registrations	0	5	23	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

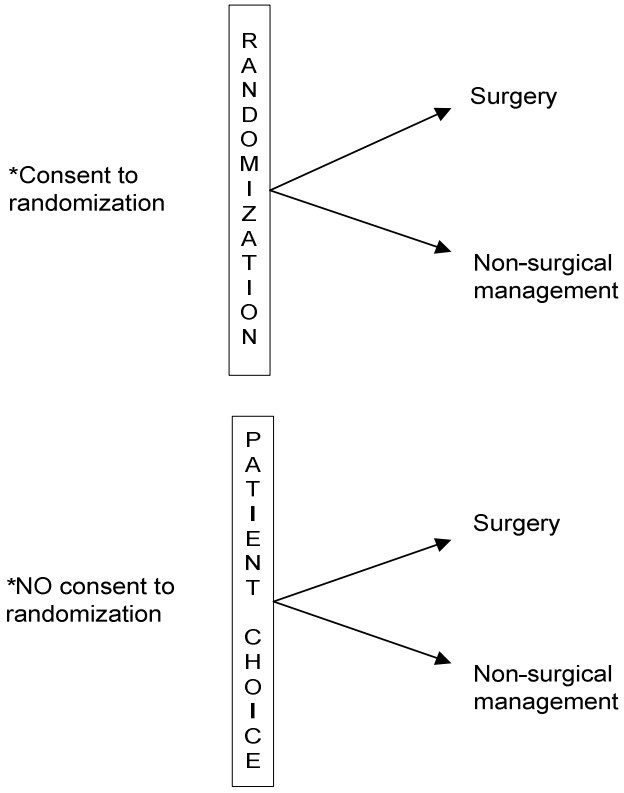
Date Activated:
03/09/2015

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

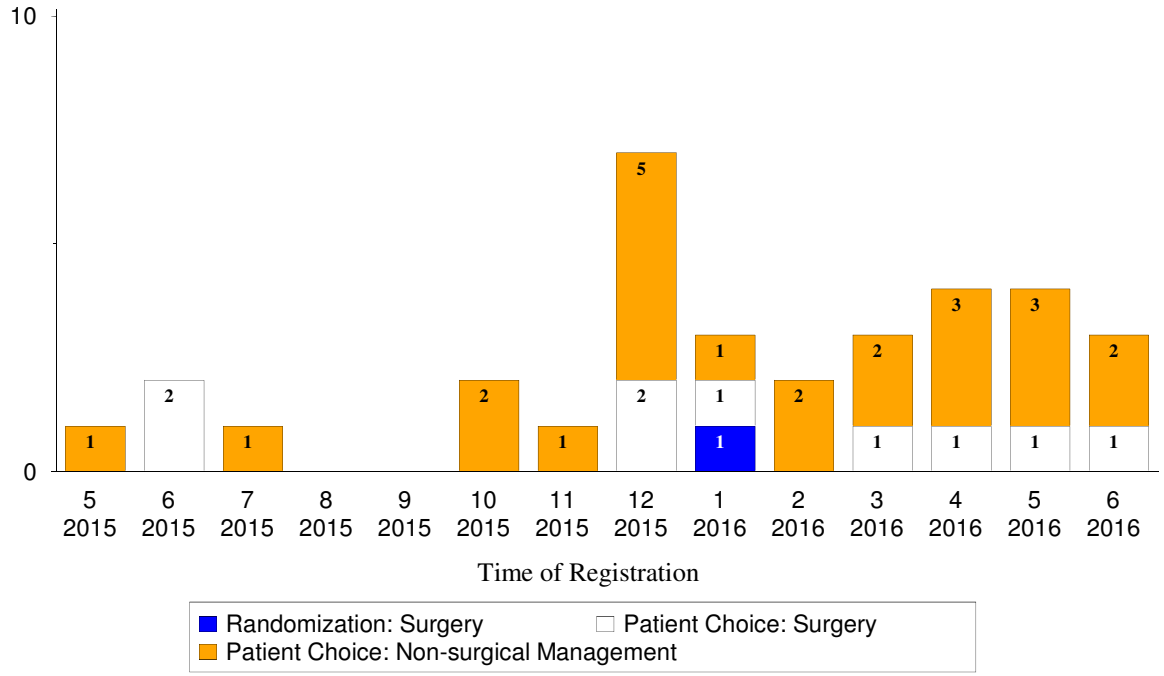
This study was activated on March 9, 2015, at limited institutions. As of June 30, 2016, 33 patients have been registered, including one patient to the randomized portion.

The one randomized patient is ineligible due to radiographic confirmation of MBO done too early. Two patients registered to the Patient Choice portion are ineligible, one due to radiographic confirmation of MBO done too early and one due to non-intra-abdominal primary cancer. Five patients have major protocol deviations: four patients who chose non-surgical management did not receive a somatostatin analogue, one of whom also received surgery; and one patient who chose non-surgical management received surgery. Twenty patients are no longer on active follow-up.

Among 18 patients who have had adverse events assessed on the non-surgical management arm, three Grade 3 events were reported for two patients: one patient reported abdominal distension and one patient reported abdominal pain and vomiting. Among seven patients who have had adverse events assessed on the surgical arm, one patient reported Grade 3 gastrointestinal fistula.

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

Initial Registrations By 1 Month Intervals



Registration by Institution

Registrations ending June 30, 2016

Institutions	Total Reg
Duke University Medical Center (NC010)	6
Medical University of South Carolina (SC008)	5
The University of Arizona Medical Center-Univer (AZ017)	5
University of Michigan Comprehensive Cancer Cen (MI014)	5
University of Arkansas for Medical Sciences (AR006)	4
Long Island Jewish Medical Center (NY065)	2
University of Oklahoma Health Sciences Center (OK003)	2
City of Hope Comprehensive Cancer Center (CA043)	1
Columbia University/Herbert Irving Cancer Cente (NY024)	1
North Shore University Hospital (NY064)	1
Rhode Island Hospital (RI005)	1
Total (11 Institutions)	**33**

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2016; Data as of July 1, 2016

	TOTAL	Randomization: Surgery	Patient Choice: Surgery	Patient Choice: Non-surgical Management
NUMBER REGISTERED	33	1	9	23
INELIGIBLE	3	1	1	1
ELIGIBLE	30	0	8	22
Analyzable, Pend. Elig.	3	0	0	3
ADVERSE EVENT ASSESSMENT				
Evaluable	25	0	7	18
Too Early	5	0	1	4

Patient Characteristics

Registrations ending June 30, 2016; Data as of July 1, 2016

	Patient Choice: Surgery (n=8)		Patient Choice: Non-surgical Management (n=22)	
AGE				
Median	67.3		60.1	
Minimum	51.8		37.9	
Maximum	90.8		85.7	
SEX				
Males	3	38%	5	23%
Females	5	63%	17	77%
HISPANIC				
Yes	1	13%	4	18%
No	7	88%	17	77%
Unknown	0	0%	1	5%
RACE				
White	7	88%	16	73%
Black	0	0%	5	23%
Pacific Islander	0	0%	1	5%
Unknown	1	13%	0	0%
PRIMARY TUMOR TYPE				
Colorectal cancer	3	38%	3	14%
Ovarian cancer	2	25%	5	23%
Other cancer	3	38%	14	64%

Treatment Summary

Registrations ending June 30, 2016; Data as of July 1, 2016

	TOTAL	Patient Choice: Surgery	Patient Choice: Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	10	5	5
NUMBER OFF PROTOCOL TREATMENT	20	3	17
REASON OFF TREATMENT			
Treatment completed as planned	0	0	0
Adverse Event or side effects	3	1	2
Refusal unrelated to adverse event	2	0	2
Progression/relapse	1	0	1
Death	9	2	7
Other - not protocol specified	0	0	0
Reason under review	5	0	5
MAJOR PROTOCOL DEVIATIONS	5	0	5

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

Adverse Events Unlikely or Not Related to Treatment Excluded

Registrations ending June 30, 2016; Data as of July 1, 2016

	Patient Choice: Surgery (n=7) Grade						Patient Choice: Non-surgical Management (n=18) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal distension	7	0	0	0	0	0	17	0	0	1	0	0
Abdominal pain	7	0	0	0	0	0	16	0	1	1	0	0
Diarrhea	7	0	0	0	0	0	17	0	1	0	0	0
Gastrointestinal fistula	6	0	0	1	0	0	18	0	0	0	0	0
Nausea	7	0	0	0	0	0	17	0	1	0	0	0
Vomiting	7	0	0	0	0	0	17	0	0	1	0	0
Wound dehiscence	6	0	1	0	0	0	18	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	6	0	0	1	0	0	16	0	0	2	0	0

S1501 Phase III

Coordinating Group: SWOG

Prospective Evaluation of Carvedilol in Prevention of Cardiac Toxicity in Patients with Metastatic HER-2+ Breast Cancer, Phase III

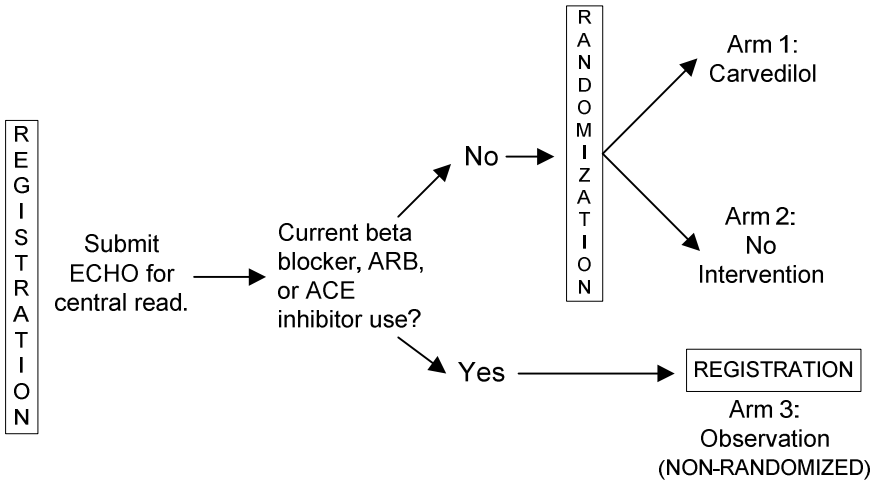
Participants:
SWOG, CTSU

Study Chairs:
J Floyd, M Leja

Statisticians:
K Guthrie, A Darke

Data Coordinator:
R Topacio

SCHEMA



Objectives

To assess whether prophylactic beta blocker therapy with carvedilol compared with no intervention reduces the risk of subsequent cardiac dysfunction in patients with metastatic breast cancer receiving trastuzumab-based HER-2 targeted therapy.

To assess whether prophylactic beta blocker therapy with carvedilol compared with no intervention reduces the risk of predefined subsequent cardiac events in patients with metastatic breast cancer receiving trastuzumab-based HER-2 targeted therapy.

To evaluate if prophylactic carvedilol compared with no intervention results in a longer time to first interruption of trastuzumab-based HER-2 targeted therapy due to either cardiac dysfunction or events.

To assess whether prophylactic beta blocker therapy with carvedilol compared with no intervention reduces the risk of subsequent cardiac dysfunction OR events in this population.

To establish and prospectively collect a predefined panel of baseline core cardiovascular measures and develop a predictive model of cardiac dysfunction.

To evaluate the rate of cardiac dysfunction in an observational arm consisting of individuals otherwise eligible for the study except for use of beta blockers, angiotensin receptor blocker (ARB), or angiotensin converting enzyme (ACE) inhibitors for other medical reasons.

Patient Population

Patients must have HER-2 positive metastatic breast cancer. Patients must be at increased risk of cardiotoxicity, due to past, current, or planned anthracycline exposure, or due to at least one risk factor for heart disease as specified in the protocol.

Patients must be initiating or continuing trastuzumab-based HER-2 targeted therapy in first or second line setting. To participate in the randomized portion of the study, patients must not have taken within 21 days, be taking, or be planning to take once registered an ARB, ACE inhibitor, or beta blocker. To participate in the observational portion of the study, patients must be currently taking an ARB, ACE inhibitor, or beta blocker and plan to continue this medication once registered.

Patients must be 18 years or older and must have a Zubrod Performance Status of 0, 1, or 2. Patients must have LVEF $\geq$ 50% by 2-D echocardiogram obtained from an S1501 validated ECHO lab. Patients must have systolic blood pressure $\geq$ 80 mm Hg and must be able to swallow tablets. Patients must not be dialysis dependent, have uncontrolled asthma, or co-enroll on other treatment trials.

Stratification/Descriptive Factors

Patient randomization will be stratified by the following factors: (1) current, prior, or planned anthracycline therapy: yes vs no and (2) baseline LVEF by S1501 ECHO Core Lab central read: 50%-54% vs $\geq$ 55%.

Accrual Goals

A total of 667 patients will be accrued to achieve 633 eligible patients in the randomized cohort; 150 patients will be accrued to the observational cohort. An interim futility analysis will be performed when 400 patients have been accrued to the randomized cohort.