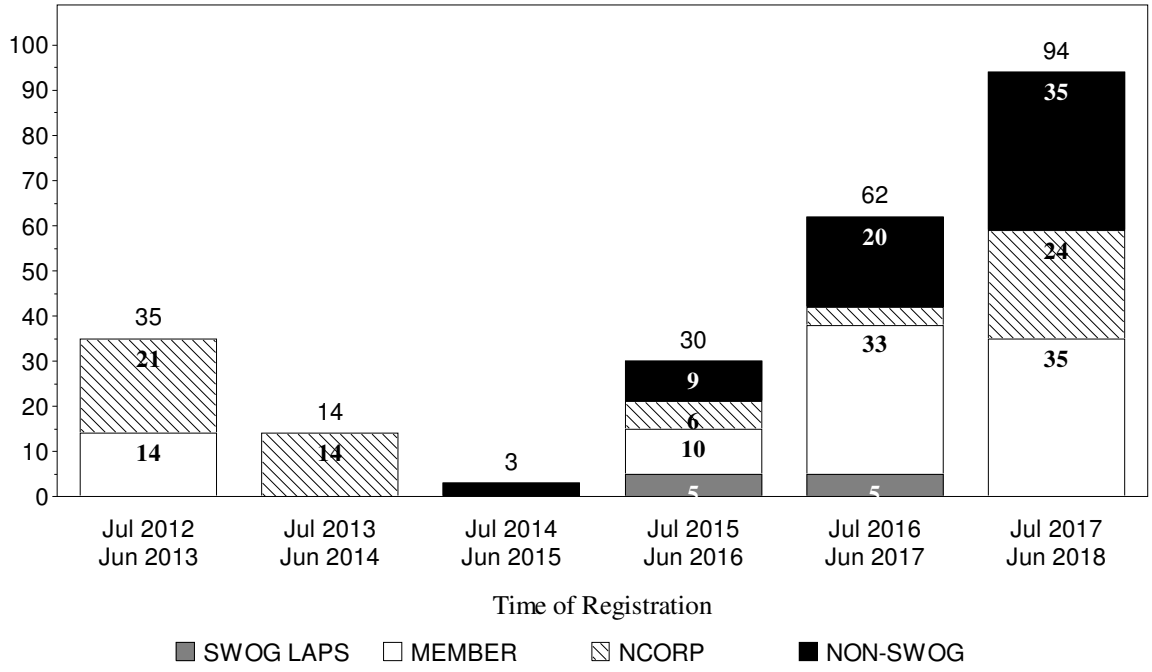
CANCER SURVIVORSHIP COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
CANCER SURVIVORSHIP COMMITTEE
As Primary Committee



Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

CANCER SURVIVORSHIP COMMITTEE

	Jan 2018 Jun 2018	Jul 2017 Dec 2017	Jan 2017 Jun 2017	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Randomization Surgery	1	3	0	5
Randomization Non-surgical Management	0	4	1	5
Patient Choice Surgery	8	8	12	45
Patient Choice Non-surgical Management	16	24	22	100
	25	39	35	155
S1501 Surv, Breast Stg IV, Card Tox w/ Carvedilol				
Screening Registration				
Screening	14	3	0	17
Registration/Randomization				
Carvedilol	1	1	0	2
No intervention	2	1	0	3
Observation	9	1	0	10
	12	3	0	15

Non-SWOG Studies with SWOG-Credited Registrations

CANCER SURVIVORSHIP COMMITTEE

Studies with Accrual from January 2017 - June 2018

	SWOG Champion	SWOG Accrual Jan 2018 Jun 2018	SWOG Accrual Jul 2017 Dec 2017	SWOG Total	Total Accrued
A221405 Breast, ET interruption, Pregnancy Outcomes*		1	6	11	61
Date Activated: 10/15/15					
No Progress Report Available					
E1Q11 EROS: Reproductive Health in Cancer Survivors		4	3	12	206
Date Activated: 09/30/15					
Most Recent Progress Report					
EA9131 Leuk, Strategy to decrease early APL deaths		6	2	9	37
Date Activated: 08/16/17					
Most Recent Progress Report					

* Studies with Cancer Survivorship as a secondary committee

S1008 Phase II

Feasibility Study of a Physical Activity and Dietary Change Weight Loss Intervention in Breast and Colorectal Cancer Survivors, Phase II

Study Chairs:
H Greenlee, D Hershman

Statisticians:
D Lew, J Unger

Data Coordinator:
R Topacio

Date Activated:
03/01/2012

Date Closed:
07/01/2014

Objectives

To determine the feasibility of a 12-month community-situated combined physical activity and dietary change weight loss intervention in overweight and sedentary female breast and colorectal cancer survivors recruited via SWOG. Feasibility will be assessed based on study accrual, intervention adherence, and study retention. Analyses will be conducted separately for breast and colorectal cancer survivors.

To estimate the effect size of the intervention on weight loss at 12 months.

To measure changes from baseline to 6 and 12 months in anthropometric measures (body mass index [BMI], waist and hip circumference) and changes from baseline to 12 months in body composition (% body fat as assessed by DXA scan).

To measure changes from baseline to 6 and 12 months in minutes spent per week in moderate-to-vigorous aerobic activity using Curves® attendance records and a 7-day physical activity assessment.

To measure changes from baseline to 6 and 12 months in self-reported dietary intake via three separate 24-hour diet recalls at each time point.

To measure changes from baseline to 6 and 12 months in dietary intake of carotenoids via serum carotenoid measures.

To measure changes from baseline to 6 and 12 months in metabolic and hormonal biomarkers associated with breast and colorectal cancer recurrence risk (fasting insulin, fasting glucose, hemoglobin A1C, bioavailable estradiol, free testosterone, and adiponectin).

To assess changes from baseline to 6 and 12 months in anxiety, depression, fatigue, sleep, satisfaction with social roles, pain and physical function using the PROMIS-43.

To assess changes from baseline to 6 and 12 months in perceived benefit of dietary change, physical activity and weight loss after a cancer diagnosis.

To assess the diversity of subjects who enroll and complete the intervention.

To assess baseline predictors (medical history, health behaviors, quality of life) of subjects who adhere to and complete the intervention.

To assess the safety of the Curves® fitness centers for this population by assessing self-reported changes in lymphedema and any injuries as measured at 6 and 12 months.

To assess the availability and acceptability of the Curves® fitness centers at 12 months.

To assess the acceptability of the dietary change component of the intervention at 12 months.

To explore changes in DNA methylation.

To assess the intervention and study process via open-ended interviews with SWOG sites and Curves® franchises.

To measure changes in anthropometric measures and assess feasibility of extended follow-up at 24 and 36 months.

Patient Population

Participants must be women with a previous diagnosis of invasive breast cancer or colorectal cancer, Stage I, II, or III, with no evidence of metastatic disease (M0). Participants must have no evidence of disease at the time of registration and no history of metastases. Participants must be post-menopausal as defined in the protocol.

Participants must be 90 days to 7 years post-surgery, chemotherapy, and radiation therapy. Concurrent cytotoxic therapies, including Herceptin, are not allowed among breast cancer patients. Other concurrent therapies are allowed among breast cancer patients, including IV bisphosphonates (e.g., Zometa), RANK ligand inhibitors (e.g., Xgeva, Prolia), and anti-hormonal therapies (e.g., aromatase inhibitors). Participants must not have had weight loss surgery.

Participants must be considered sedentary as defined in the protocol, have a BMI $\geq$ 25 kg/m2 and a Zubrod performance status of 0. Participants must have no abnormal changes on cardiovascular exercise stress test as measured by EKG. Participants must not be active smokers or have evidence of uncontrolled hypertension. Participants with diabetes, pre-diabetes, and/or metabolic syndrome must have HgbA1C $\leq$ 8. Participants must be willing and able to attend a Curves® fitness center at least three times per week for 12 months and agree to participate in the behavioral counseling sessions and telephone interviews. Participants must be willing to submit blood samples for biomarkers. Participants must have physician clearance to participate, regular access to the internet, a home phone or cell phone, and be able to understand, speak and read English.

Stratification/Descriptive Factors

Participants will be stratified at time of registration by type of cancer: breast vs colorectal.

Accrual Goals

The accrual goal is 25 eligible breast cancer survivors and 25 eligible colorectal cancer survivors.

Summary Statement

This study was activated March 1, 2012, to limited institutions and enrolled 50 participants prior to closure on July 1, 2014: 26 breast cancer survivors in 10 months and 24 colorectal cancer survivors in 24 months. One participant who was removed from protocol prior to starting study intervention is not analyzable and was replaced within the breast cancer survivor cohort. One participant in the colorectal cancer survivor cohort who did not receive any study intervention after experiencing disease progression soon after enrollment is also not analyzable. Two participants who were removed from study intervention due to inability to exercise because of foot injuries are shown in the table as reason "Other - not protocol specified."

Participants were asked about lymphedema symptoms at baseline, six, and 12 months. The breast cancer group reported three exacerbations of previous cancer-related lymphedema and one new onset lymphedema, whereas the colorectal cancer group reported no lymphedema.

The results of the primary objectives for this trial for both cohorts were accepted for publication in Obesity in July 2018.

Among 25 breast cancer survivors, median baseline BMI was 37.2 kg/m^2 (range 27.7-54.6), accrual occurred in 10 months, 80% of participants provided anthropometric measures at 12 months, 60% and 28% met diet and exercise goals, and average weight loss was 7.6% (95% CI -3.9%, 19.2%).

Among 23 colorectal cancer survivors, median baseline BMI was 31.8 kg/m^2 (range 26.4-48.7), accrual occurred in 24 months, 87% of participants provided anthropometric measures at 12 months, 61% and 17% met diet and exercise goals, and average weight loss was 2.5% (95% CI -8.2%, 13.3%).

Conclusion: It is feasible to recruit and retain breast cancer survivors in a cooperative group diet and physical exercise weight loss trial. Breast cancer survivors achieved clinically meaningful weight loss but did not meet a priori adherence goals. In colorectal cancer survivors, recruitment was more difficult and the intervention less effective.

Registration by Institution

Institutions	Total Reg	Institutions	Total Reg
Kaiser Perm NCORP	20	Beaumont NCORP	3
Loyola University	8	PCRC NCORP	3
Kansas, U of	6	Arizona MC, U of	1
Greenville NCORP	4	Columbia MU-NCORP	1
Wichita NCORP	4	**Total (9 Institutions)**	**50**

Registration, Eligibility, and Evaluability

Classified by Disease Cohort
Data as of August 31, 2018

	TOTAL	Breast	Colorectal
NUMBER REGISTERED	50	26	24
ELIGIBLE	50	26	24
Not Analyzable	2	1	1

Patient Characteristics

Classified by Disease Cohort
Data as of August 31, 2018

	Breast (n=25)		Colorectal (n=23)	
AGE				
Median	57.2		64.4	
Minimum	32.9		50.5	
Maximum	70.8		78.2	
HISPANIC				
Yes	1	4%	2	9%
No	24	96%	21	91%
RACE				
White	22	88%	19	83%
Black	3	12%	1	4%
Asian	0	0%	1	4%
Native American	0	0%	1	4%
Unknown	0	0%	1	4%
BMI (kg/m^2)				
Median	37.2		31.8	
Minimum	27.7		26.4	
Maximum	54.6		48.7	

Treatment Summary

Classified by Disease Cohort
Data as of August 31, 2018

	TOTAL	Breast	Colorectal
NUMBER ON PROTOCOL TREATMENT	0	0	0
NUMBER OFF PROTOCOL TREATMENT	48	25	23
REASON OFF TREATMENT			
Treatment completed as planned	36	16	20
Adverse Event or side effects	0	0	0
Refusal unrelated to adverse event	10	7	3
Progression/relapse	0	0	0
Death	0	0	0
Other - not protocol specified	2	2	0
Reason under review	0	0	0
MAJOR PROTOCOL DEVIATIONS	0	0	0

Analysis Results

Classified by Disease Cohort

	Breast (n=25)		Colorectal (n=23)	
INTERVENTION GOALS MET				
Diet	15	60%	14	61%
Exercise	7	28%	4	17%
ANTHROPOMETRIC MEASURES PROVIDED				
Baseline	25	100%	23	100%
6 months	22	88%	21	91%
12 months	20	80%	20	87%
WEIGHT LOSS (kg)				
Baseline	98.1		85.4	
6 months mean change from baseline	5.5	5.5%	2.5	2.8%
12 months mean change from baseline	7.8	7.6%	2.1	2.5%

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

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Participants:
SWOG, CTSU (Supported by Alliance)

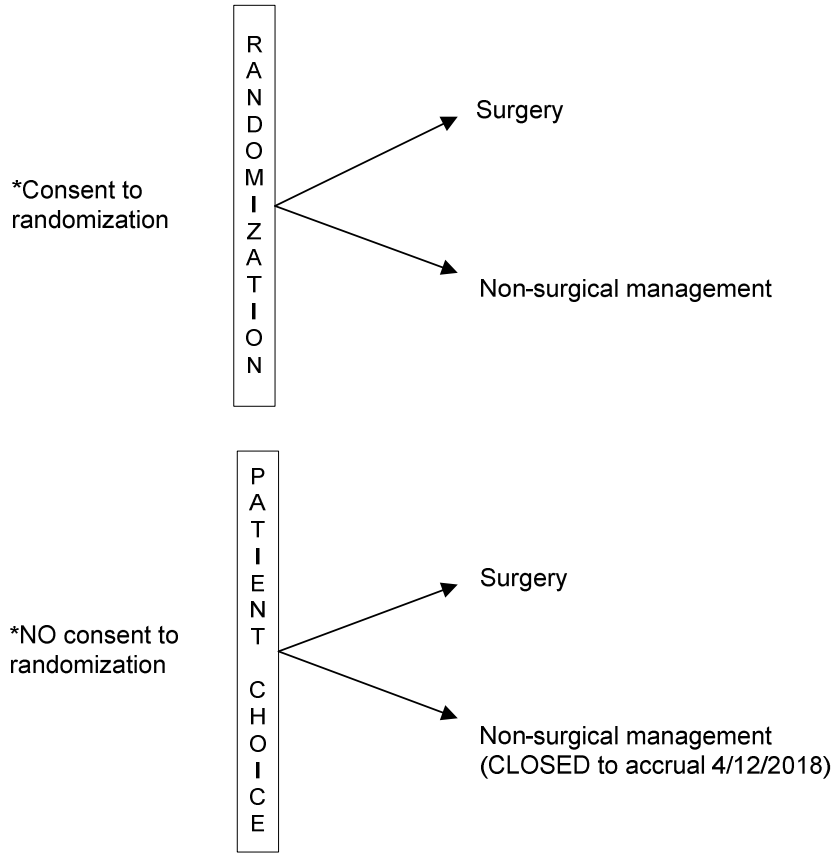
Date Activated:
03/09/2015

Study Chairs:
R Krouse, 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 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 200 patients will be accrued to achieve 180 eligible patients, with a target of 34 patients in the randomized component.

Summary Statement

This study was activated on March 9, 2015, at limited institutions. After a seven week temporary closure, the study reopend to accural on June 1, 2018, with the Patient Choice Non-surgical Management arm permanently closed. As of June 30, 2018, 155 patients have been registered at 23 institutions, including ten patients to the randomized portion.

Two patients registered to the Patient Choice Surgery arm are ineligible due to surgery prior to registration. 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 141 eligible in the Patient Choice group, 43 (30%) chose surgery at time of consent.

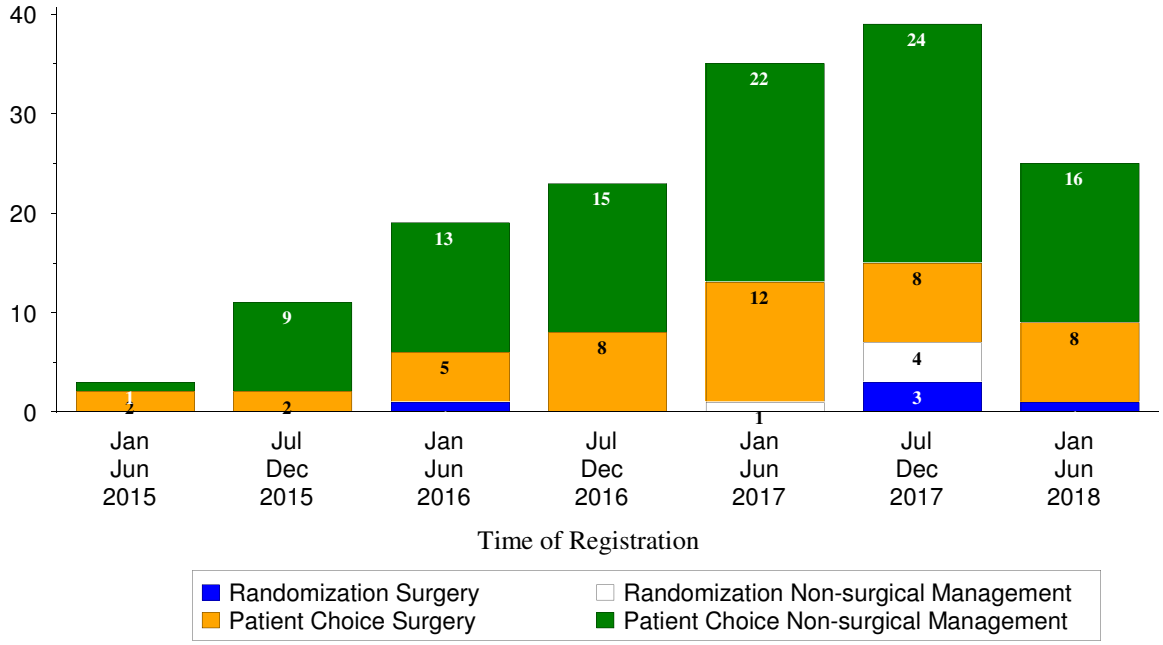
One patient randomized to non-surgical management had a major protocol deviation due to receiving surgery. One patient on the Patient Choice Surgery arm had a major protocol deviation due to not having surgery. Eighteen patients on the Patient Choice Non-surgical Management arm have major protocol deviations: eight patients did not receive a somatostatin analogue, one of whom also received surgery (somatostatin analogue use was required for non-surgical management patients registered prior to September 1, 2016), and ten patients received surgery. Twenty-five patients are actively being followed and completing study questionnaires and

dietary recalls. Ten 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: surgery vs non-surgical management. Among 47 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 100 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 June 30, 2018

Institutions	Total Reg
SWOG	89
NRG	49
ALLIANCE	17
Total (3 Network Groups)	**155**

Registration by Institution

Registrations ending June 30, 2018

Institutions	Total Reg
The West Clinic - Wolf River (TN089)	28
University of Arizona Medical Cente (AZ017)	16
University of Kansas Cancer Center (KS004)	16
North Shore University Hospital (NY064)	14
University of Oklahoma Health Scien (OK003)	13
Long Island Jewish Medical Center (NY065)	12
Duke University Medical Center (NC010)	11
City of Hope Comprehensive Cancer C (CA043)	7
University of Michigan Comprehensiv (MI014)	7
University of Arkansas for Medical (AR006)	6
Medical University of South Carolin (SC008)	5
Froedtert and the Medical College o (WI013)	4
Valley Health / Winchester Medical Center (VA008)	3
Baylor University Medical Center (TX012)	2
Moffitt Cancer Center (FL065)	2
Rhode Island Hospital (RI005)	2
Baylor College of Medicine/Dan L Du (TX041)	1
Columbia University/Herbert Irving Cancer Cente (NY024)	1
Essentia Health Cancer Center (MN024)	1
M D Anderson Cancer Center (TX035)	1
Rush University Medical Center (IL043)	1
University of New Mexico Cancer Cen (NM004)	1
University of Tennessee Health Scie (TN030)	1
Total (23 Institutions)	**155**

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2018; Data as of July 13, 2018

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER REGISTERED	155	5	5	45	100
INELIGIBLE	4	0	0	2	2
ELIGIBLE	151	5	5	43	98
ADVERSE EVENT ASSESSMENT					
Evaluable	147	5	5	42	95
Too Early	4	0	0	1	3

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 13, 2018

	Randomization Surgery (n=5)		Randomization Non-surgical Management (n=5)		Patient Choice Surgery (n=43)		Patient Choice Non-surgical Management (n=98)	
AGE								
Median	71.5		62.3		60.7		59.3	
Minimum	54.4		47.8		33.3		32.7	
Maximum	84.7		77.5		90.8		85.6	
SEX								
Males	2	40%	4	80%	18	42%	31	32%
Females	3	60%	1	20%	25	58%	67	68%
HISPANIC								
Yes	0	0%	0	0%	5	12%	14	14%
No	5	100%	5	100%	37	86%	82	84%
Unknown	0	0%	0	0%	1	2%	2	2%
RACE								
White	3	60%	2	40%	30	70%	72	73%
Black	2	40%	3	60%	10	23%	16	16%
Asian	0	0%	0	0%	0	0%	2	2%
Pacific Islander	0	0%	0	0%	0	0%	2	2%
Native American	0	0%	0	0%	0	0%	1	1%
Unknown	0	0%	0	0%	3	7%	5	5%
PRIMARY TUMOR TYPE								
Colorectal cancer	3	60%	4	80%	14	33%	26	27%
Ovarian cancer	0	0%	0	0%	6	14%	35	36%
Other cancer	2	40%	1	20%	23	53%	37	38%

Treatment Summary

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 13, 2018

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	25	0	1	12	12
NUMBER OFF PROTOCOL TREATMENT	126	5	4	31	86
REASON OFF TREATMENT					
Treatment completed as planned	9	0	0	5	4
Adverse Event or side effects	0	0	0	0	0
Refusal unrelated to adverse event	22	1	0	4	17
Progression/relapse	11	0	1	3	7
Death	83	4	3	19	57
Other - not protocol specified	0	0	0	0	0
Reason under review	1	0	0	0	1
MAJOR PROTOCOL DEVIATIONS	20	0	1	1	18

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

Classified by Treatment Type

Adverse Events Unlikely or Not Related to Treatment Excluded

All Eligible and Selected Ineligible Patients Included

Registrations ending June 30, 2018; Data as of July 13, 2018

	Surgery Arms (n=47) Grade						Non-surgical Management Arms (n=100) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal infection	46	0	0	1	0	0	99	0	0	1	0	0
Abdominal pain	47	0	0	0	0	0	99	0	0	1	0	0
Anemia	39	1	1	5	1	0	95	0	2	2	1	0
Aspiration	46	0	1	0	0	0	99	0	1	0	0	0
Cardiac arrest	47	0	0	0	0	0	99	0	0	0	0	1
Diarrhea	47	0	0	0	0	0	99	0	1	0	0	0
Esophageal ulcer	47	0	0	0	0	0	99	1	0	0	0	0
Fever	46	1	0	0	0	0	99	0	1	0	0	0
GI disorders-Other, specify	46	0	1	0	0	0	100	0	0	0	0	0
Gastric ulcer	47	0	0	0	0	0	99	1	0	0	0	0
Gastrointestinal fistula	44	0	1	2	0	0	100	0	0	0	0	0
Gastrointestinal pain	47	0	0	0	0	0	97	1	0	2	0	0
Ileus	46	0	0	1	0	0	99	0	0	1	0	0
Myocardial infarction	46	0	0	0	1	0	100	0	0	0	0	0
Nausea	47	0	0	0	0	0	99	0	1	0	0	0
Peritoneal infection	46	0	0	1	0	0	100	0	0	0	0	0
Pneumonitis	47	0	0	0	0	0	99	0	0	0	0	1
Postoperative hemorrhage	47	0	0	0	0	0	99	0	0	0	1	0
Sepsis	47	0	0	0	0	0	99	0	0	0	0	1
Sinus bradycardia	47	0	0	0	0	0	98	2	0	0	0	0
Urinary tract infection	46	0	0	1	0	0	100	0	0	0	0	0
Vomiting	47	0	0	0	0	0	99	0	0	1	0	0
Wound complication	44	0	3	0	0	0	100	0	0	0	0	0
Wound dehiscence	46	0	1	0	0	0	99	0	1	0	0	0
Wound infection	46	0	0	1	0	0	99	0	1	0	0	0
MAX. GRADE ANY ADVERSE EVENT	36	1	1	7	2	0	88	2	3	5	1	1

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

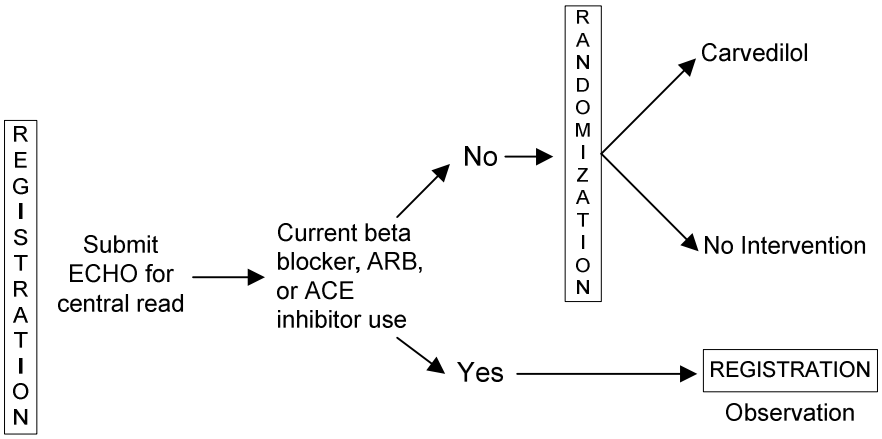
Date Activated:
09/15/2017

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 previous 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. Patients must not be taking or planning to take anthracyclines. 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 ≥ 50% by 2-D echocardiogram obtained from an S1501 validated ECHO lab. Patients must have systolic blood pressure ≥ 80 mm Hg and must be able to swallow tablets. Patients must not be dialysis dependent, have uncontrolled asthma, or be currently enrolled or plan to enroll on other treatment trials.

Stratification/Descriptive Factors

Patient randomization will be stratified by the following factors: (1) prior anthracycline therapy: yes vs no; and (2) baseline LVEF by S1501 ECHO Core Lab central read: 50%-54% vs ≥ 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.

Summary Statement

This study was activated on September 15, 2017. As of June 30, 2018, fifteen patients had been accrued: five to the randomized cohort and ten to the observational cohort. One patient on the carvedilol arm is not eligible because the baseline ECHO was completed after randomization.

Registration by Institution

Registrations ending June 30, 2018

Institutions	Total Reg
Heartland NCORP	6
Kansas, U of	2
Lahey Hosp & Med Ctr	2
Loyola University	2
Greenville NCORP	1
Providence Hosp	1
ALLIANCE	1
Total (7 Institutions)	**15**

Registration, Eligibility, and Evaluability

Registrations ending June 30, 2018; Data as of July 25, 2018

	TOTAL	Randomized Carvedilol	Randomized No intervention	Observation Arm
NUMBER REGISTERED	15	2	3	10
ELIGIBLE	15	2	3	10
Analyzable, Pend. Elig.	4	0	0	4
Not Analyzable	1	1	0	0
ADVERSE EVENT ASSESSMENT				
Evaluable	5	1	3	1
Too Early	9	0	0	9

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending June 30, 2018; Data as of July 25, 2018

	Carvedilol (n=1)		No intervention (n=3)		Observation Arm (n=10)	
AGE						
Median	48.6		59.6		58.8	
Minimum	48.6		54.9		32.4	
Maximum	48.6		86.9		77.6	
SEX						
Females	1	100%	3	100%	10	100%
HISPANIC						
No	1	100%	3	100%	10	100%
RACE						
White	1	100%	3	100%	9	90%
Black	0	0%	0	0%	1	10%
PRIOR ANTHRACYCLINES USE						
Yes	1	100%	1	33%	0	0%
No	0	0%	2	67%	10	100%
LVEF						
55% or higher	1	100%	3	100%	10	100%

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

All Eligible and Selected Ineligible Patients Included

Registrations ending June 30, 2018; Data as of July 25, 2018

	Carvedilol (n=1) Grade						No intervention (n=3) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Alkaline phosphatase increased	1	0	0	0	0	0	3	0	0	0	0	0
Chest wall pain	1	0	0	0	0	0	2	1	0	0	0	0
Dizziness	0	1	0	0	0	0	2	1	0	0	0	0
Fatigue	0	1	0	0	0	0	1	2	0	0	0	0
Generalized muscle weakness	1	0	0	0	0	0	2	1	0	0	0	0
Hot flashes	0	1	0	0	0	0	3	0	0	0	0	0
Hyperglycemia	1	0	0	0	0	0	1	2	0	0	0	0
Hypoalbuminemia	1	0	0	0	0	0	2	1	0	0	0	0
Hypokalemia	1	0	0	0	0	0	2	1	0	0	0	0
Infections/infestations-Other	1	0	0	0	0	0	2	0	1	0	0	0
Mucosal infection	1	0	0	0	0	0	2	0	1	0	0	0
Mucositis oral	1	0	0	0	0	0	2	1	0	0	0	0
Nausea	1	0	0	0	0	0	2	1	0	0	0	0
Pain	1	0	0	0	0	0	2	0	1	0	0	0
Renal/urinary disorders-Other	1	0	0	0	0	0	2	1	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	0	1	0	0	0	0	0	1	2	0	0	0

	Observation Arm (n=1) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**
Alkaline phosphatase increased	0	1	0	0	0	0
Chest wall pain	1	0	0	0	0	0
Dizziness	1	0	0	0	0	0
Fatigue	1	0	0	0	0	0
Generalized muscle weakness	1	0	0	0	0	0
Hot flashes	1	0	0	0	0	0
Hyperglycemia	0	1	0	0	0	0
Hypoalbuminemia	1	0	0	0	0	0
Hypokalemia	1	0	0	0	0	0
Infections/infestations-Other	1	0	0	0	0	0
Mucosal infection	1	0	0	0	0	0
Mucositis oral	1	0	0	0	0	0
Nausea	1	0	0	0	0	0
Pain	1	0	0	0	0	0
Renal/urinary disorders-Other	1	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	0	1	0	0	0	0