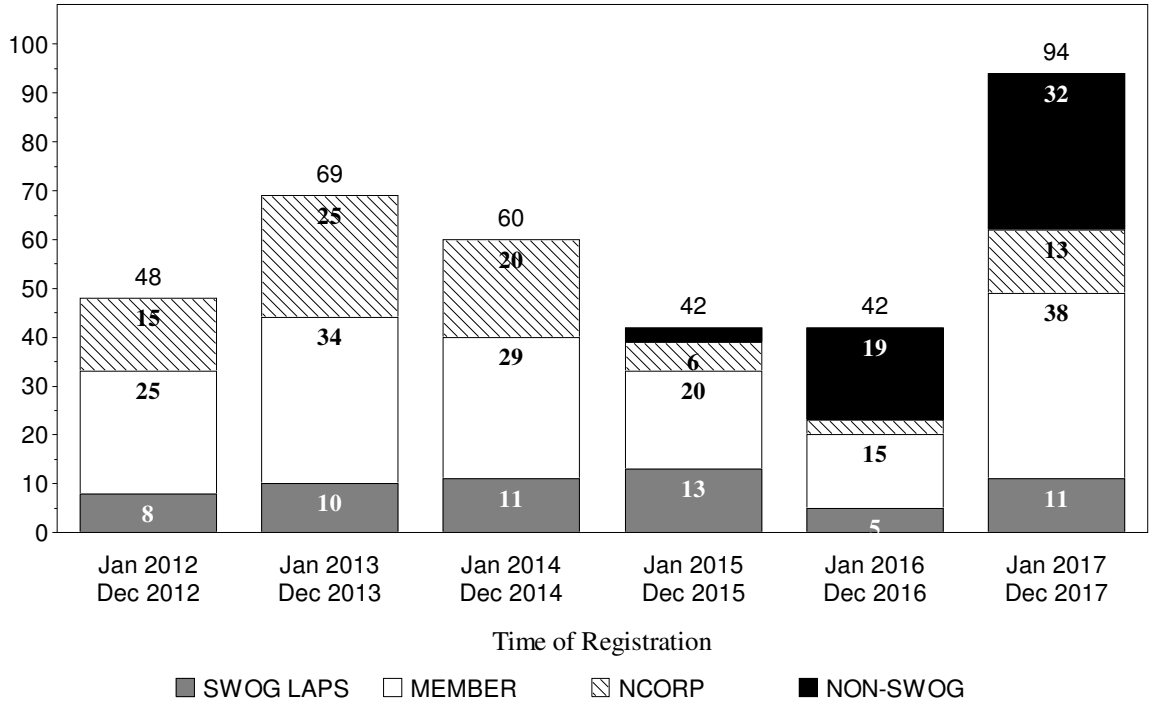
CANCER SURVIVORSHIP COMMITTEE

CONTENTS

Patient Registrations to Studies

By 12 Month Intervals
CANCER SURVIVORSHIP COMMITTEE



Screening registrations and registrations to Biologic only studies are excluded.

Patient Registrations by Study and Arm

CANCER SURVIVORSHIP COMMITTEE

	Jul 2017 Dec 2017	Jan 2017 Jun 2017	Jul 2016 Dec 2016	All Patients
S1316 Compar. Effectiv. Trial for MBO				
Registration				
Randomization Surgery	3	0	0	4
Randomization Non-surgical Management	4	1	0	5
Patient Choice Surgery	8	12	8	37
Patient Choice Non-surgical Management	24	22	15	84
	39	35	23	130
S1501 Surv, Breast Stg IV, Card Tox w/ Carvedilol				
Screening Registration				
Screening	3	0	0	3
Registration/Randomization				
Carvedilol	1	0	0	1
No intervention	1	0	0	1
Observation	1	0	0	1
	3	0	0	3
A221405 Breast, ET interruption, Pregnancy Outcomes*				
Total Registrations	6	2	0	8
E1Q11 EROS: Reproductive Health in Cancer Survivors*				
Total Registrations	3	4	0	7
EA9131 Leuk, Strategy to decrease early APL deaths*				
Total Registrations	2	0	0	2

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

Non-SWOG Studies with SWOG-Credited Registrations

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Studies with Accrual from July 2016 - December 2017

	SWOG Champion	Date Activated	Date Closed	Total Accrued
A221405 Breast, ET interruption, Pregnancy Outcomes		10/15/15		48
No Progress Report Available				
E1Q11 EROS: Reproductive Health in Cancer Survivors		09/30/15		123
Most Recent Progress Report				
EA9131 Leuk, Strategy to decrease early APL deaths		08/16/17		11
No Progress Report Available				

S1316 Pilot

Coordinating Group: SWOG

Prospective Comparative Effectiveness Trial For Malignant Bowel Obstruction

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Participants:
SWOG, CTSU (Supported by Alliance)

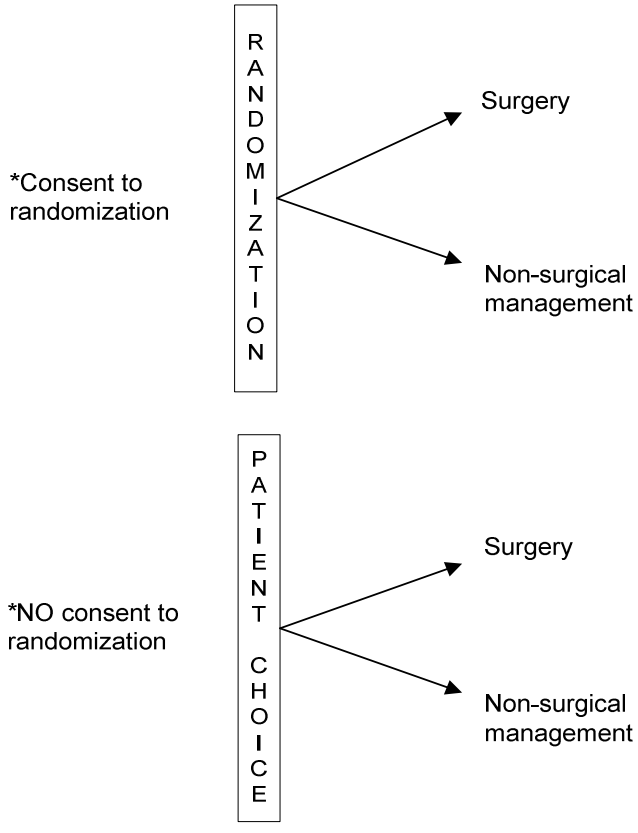
Date Activated:
03/09/2015

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 at least 50 eligible patients in the randomized component.

Summary Statement

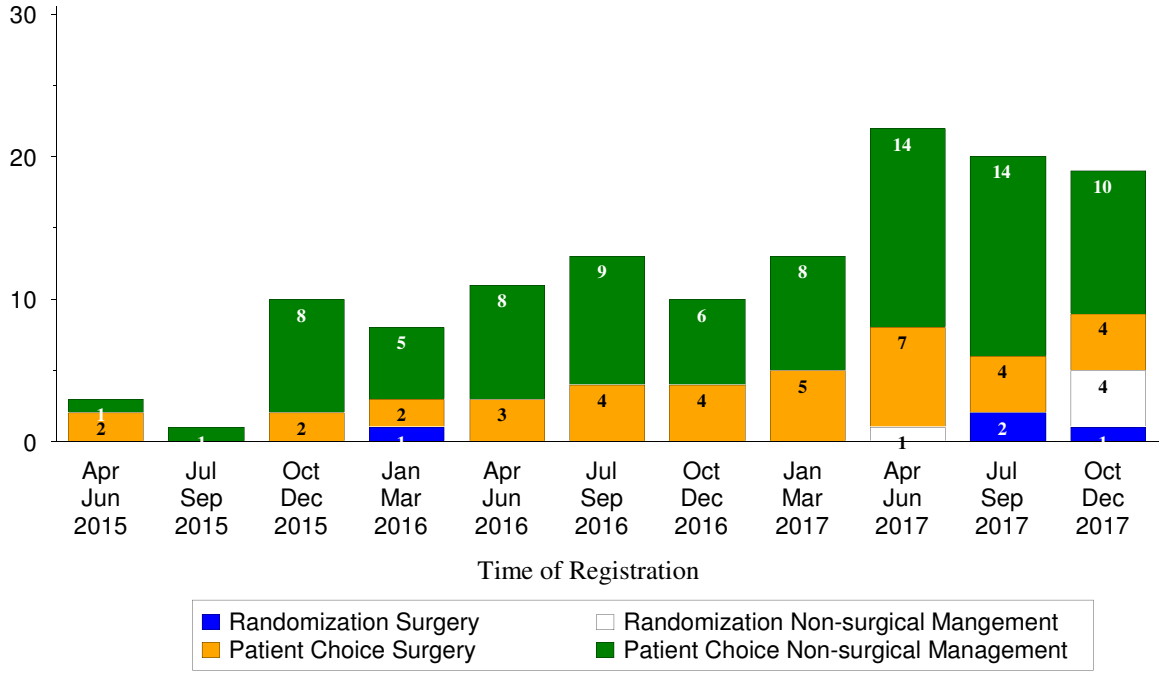
This study was activated on March 9, 2015, at limited institutions. As of December 31, 2017, 130 patients have been registered, including nine patients to the randomized portion.

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 117 eligible in the Patient Choice group, 35 (30%) chose surgery at time of consent.

One patient on the Patient Choice Surgery arm had a major protocol deviation due to not having surgery. Sixteen 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 eight patients received surgery. Thirty-three patients are actively being followed and completing study questionnaires and dietary recalls. Seven patients who are off treatment for various reasons have withdrawn consent for any further follow-up.

Among four patients randomized to surgery who have had adverse events assessed, one patient experienced Grade 4 anemia. No adverse events were reported for the five patients randomized to non-surgical management who have had adverse events assessed. Among 34 patients who have had adverse events assessed on the Patient Choice Surgery arm, no Grade 4 or 5 events were reported. Among 78 patients who have had adverse events assessed on the Patient Choice Non-surgical Management arm, one patient had Grade 5 sepsis, pneumonitis and cardiac arrest, and one patient experienced Grade 4 anemia and post-operative hemorrhage.

Initial Registrations By 3 Month Intervals



Registration by Network Groups

Registrations ending December 31, 2017

Institutions	Total Reg
SWOG	76
NRG	39
ALLIANCE	15
Total (4 Network Groups)	**130**

Registration by Institution

Registrations ending December 31, 2017

Institutions	Total Reg
The West Clinic - Wolf River (TN089)	24
University of Kansas Cancer Center (KS004)	14
North Shore University Hospital (NY064)	12
University of Arizona Medical Cente (AZ017)	12
University of Oklahoma Health Scien (OK003)	12
Long Island Jewish Medical Center (NY065)	10
Duke University Medical Center (NC010)	8
City of Hope Comprehensive Cancer C (CA043)	7
University of Michigan Comprehensiv (MI014)	7
Medical University of South Carolin (SC008)	5
University of Arkansas for Medical (AR006)	5
Froedtert and the Medical College o (WI013)	3
Baylor University Medical Center (TX012)	2
Rhode Island Hospital (RI005)	2
Baylor College of Medicine/Dan L Du (TX041)	1
Columbia University/Herbert Irving (NY024)	1
Essentia Health Cancer Center (MN024)	1
M D Anderson Cancer Center (TX035)	1
Moffitt Cancer Center (FL065)	1
Rush University Medical Center (IL043)	1
University of Tennessee Health Scie (TN030)	1
Total (21 Institutions)	**130**

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2017; Data as of February 2, 2018

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER REGISTERED	130	4	5	37	84
INELIGIBLE	4	0	0	2	2
ELIGIBLE	126	4	5	35	82
Analyzable, Pend. Elig.	2	0	0	0	2
ADVERSE EVENT ASSESSMENT					
Evaluable	121	4	5	34	78
Too Early	5	0	0	1	4

Patient Characteristics

All eligible and selected ineligible patients included

Registrations ending December 31, 2017; Data as of February 2, 2018

	Randomization Surgery (n=4)		Randomization Non-surgical Management (n=5)		Patient Choice Surgery (n=35)		Patient Choice Non-surgical Management (n=82)	
AGE								
Median	72.5		62.4		60.7		59.9	
Minimum	54.4		47.8		33.3		32.7	
Maximum	84.7		77.5		90.8		85.7	
SEX								
Males	2	50%	4	80%	16	46%	26	32%
Females	2	50%	1	20%	19	54%	56	68%
HISPANIC								
Yes	0	0%	0	0%	3	9%	10	12%
No	4	100%	5	100%	32	91%	71	87%
Unknown	0	0%	0	0%	0	0%	1	1%
RACE								
White	2	50%	2	40%	24	69%	59	72%
Black	2	50%	3	60%	9	26%	16	20%
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%	2	6%	2	2%
PRIMARY TUMOR TYPE								
Colorectal cancer	2	50%	4	80%	9	26%	22	27%
Ovarian cancer	0	0%	0	0%	5	14%	32	39%
Other cancer	2	50%	1	20%	21	60%	28	34%

Treatment Summary

All eligible and selected ineligible patients included

Registrations ending December 31, 2017; Data as of February 2, 2018

	TOTAL	Randomization Surgery	Randomization Non-surgical Management	Patient Choice Surgery	Patient Choice Non-surgical Management
NUMBER ON PROTOCOL TREATMENT	33	1	2	10	20
NUMBER OFF PROTOCOL TREATMENT	93	3	3	25	62
REASON OFF TREATMENT					
Treatment completed as planned	6	0	0	3	3
Adverse Event or side effects	0	0	0	0	0
Refusal unrelated to adverse event	13	1	0	2	10
Progression/relapse	11	0	1	3	7
Death	62	2	2	16	42
Other - not protocol specified	0	0	0	0	0
Reason under review	1	0	0	1	0
MAJOR PROTOCOL DEVIATIONS	18	0	1	1	16

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

Adverse Events Unlikely or Not Related to Treatment Excluded

All Eligible and Selected Ineligible Patients Included

Registrations ending December 31, 2017; Data as of February 2, 2018

	Randomization Surgery (n=4) Grade						Randomization Non-surgical Management (n=5) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal infection	4	0	0	0	0	0	5	0	0	0	0	0
Abdominal pain	4	0	0	0	0	0	5	0	0	0	0	0
Anemia	2	0	0	1	1	0	5	0	0	0	0	0
Aspiration	3	0	1	0	0	0	5	0	0	0	0	0
Cardiac arrest	4	0	0	0	0	0	5	0	0	0	0	0
Diarrhea	4	0	0	0	0	0	5	0	0	0	0	0
Esophageal ulcer	4	0	0	0	0	0	5	0	0	0	0	0
Fever	4	0	0	0	0	0	5	0	0	0	0	0
GI disorders-Other, specify	4	0	0	0	0	0	5	0	0	0	0	0
Gastric ulcer	4	0	0	0	0	0	5	0	0	0	0	0
Gastrointestinal fistula	3	0	0	1	0	0	5	0	0	0	0	0
Gastrointestinal pain	4	0	0	0	0	0	5	0	0	0	0	0
Ileus	4	0	0	0	0	0	5	0	0	0	0	0
Nausea	4	0	0	0	0	0	5	0	0	0	0	0
Peritoneal infection	3	0	0	1	0	0	5	0	0	0	0	0
Pneumonitis	4	0	0	0	0	0	5	0	0	0	0	0
Postoperative hemorrhage	4	0	0	0	0	0	5	0	0	0	0	0
Sepsis	4	0	0	0	0	0	5	0	0	0	0	0
Sinus bradycardia	4	0	0	0	0	0	5	0	0	0	0	0
Urinary tract infection	3	0	0	1	0	0	5	0	0	0	0	0
Vomiting	4	0	0	0	0	0	5	0	0	0	0	0
Wound complication	4	0	0	0	0	0	5	0	0	0	0	0
Wound dehiscence	4	0	0	0	0	0	5	0	0	0	0	0
Wound infection	4	0	0	0	0	0	5	0	0	0	0	0
MAX. GRADE ANY ADVERSE EVENT	2	0	0	1	1	0	5	0	0	0	0	0

	Patient Choice Surgery (n=34) Grade						Patient Choice Non-surgical Management (n=78) Grade					
ADVERSE EVENTS	**0**	**1**	**2**	**3**	**4**	**5**	**0**	**1**	**2**	**3**	**4**	**5**
Abdominal infection	33	0	0	1	0	0	77	0	0	1	0	0
Abdominal pain	34	0	0	0	0	0	77	0	0	1	0	0
Anemia	28	1	1	4	0	0	74	0	2	1	1	0
Aspiration	34	0	0	0	0	0	77	0	1	0	0	0
Cardiac arrest	34	0	0	0	0	0	77	0	0	0	0	1
Diarrhea	34	0	0	0	0	0	77	0	1	0	0	0
Esophageal ulcer	34	0	0	0	0	0	77	1	0	0	0	0
Fever	33	1	0	0	0	0	77	0	1	0	0	0
GI disorders-Other, specify	33	0	1	0	0	0	78	0	0	0	0	0
Gastric ulcer	34	0	0	0	0	0	77	1	0	0	0	0
Gastrointestinal fistula	32	0	1	1	0	0	78	0	0	0	0	0
Gastrointestinal pain	34	0	0	0	0	0	75	1	0	2	0	0
Ileus	33	0	0	1	0	0	77	0	0	1	0	0
Nausea	34	0	0	0	0	0	77	0	1	0	0	0
Peritoneal infection	34	0	0	0	0	0	78	0	0	0	0	0
Pneumonitis	34	0	0	0	0	0	77	0	0	0	0	1
Postoperative hemorrhage	34	0	0	0	0	0	77	0	0	0	1	0
Sepsis	34	0	0	0	0	0	77	0	0	0	0	1
Sinus bradycardia	34	0	0	0	0	0	76	2	0	0	0	0
Urinary tract infection	34	0	0	0	0	0	78	0	0	0	0	0
Vomiting	34	0	0	0	0	0	77	0	0	1	0	0
Wound complication	31	0	3	0	0	0	78	0	0	0	0	0
Wound dehiscence	33	0	1	0	0	0	78	0	0	0	0	0
Wound infection	33	0	0	1	0	0	77	0	1	0	0	0
MAX. GRADE ANY ADVERSE EVENT	26	1	1	6	0	0	67	2	3	4	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

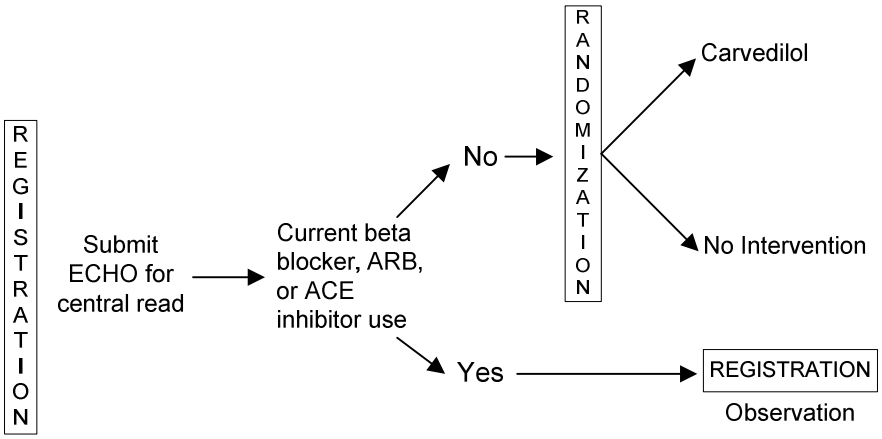
Date Activated:
09/15/2017

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 December 31, 2017, three patients had been accrued to Step 1 and Step 2. All patients are eligible and on treatment.

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2017; Data as of February 6, 2018

	Screening
NUMBER REGISTERED	3
ELIGIBLE	3

Registration, Eligibility, and Evaluability

Registrations ending December 31, 2017; Data as of February 6, 2018

	TOTAL	Carvedilol	No intervention	Observation Arm
NUMBER REGISTERED	3	1	1	1
ELIGIBLE	3	1	1	1
ADVERSE EVENT ASSESSMENT				
Too Early	3	1	1	1

Registration by Institution

Registrations ending December 31, 2017

Institutions	Total Reg
Heartland NCORP	3
Total (1 Institutions)	**3**