Cancer Research Consortium of West Michigan
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Fast Facts

WF 97415: Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT)

840 Women with Stage I – III Breast Cancer

Inclusion Criteria

• Stage I-III female breast cancer (including inflammatory and newly diagnosed, or locally recurrent but not metastatic breast cancer being treated with curative intent)
• > 18 years old
• Scheduled to receive chemotherapy and/or estrogen antagonist aromatase inhibitors (anastrozole [Arimidex], letrozole [Femara], exemestane [Aromasin]).
• Able to hold breath for 10 seconds
• ECOG performance status 0 – 2*
• Able to walk at least 2 blocks without chest pain, dyspnea, shortness of breath or fainting
• Able to exercise on a treadmill or stationary cycle
• Participants in other ongoing clinical trials are eligible for this study

Exclusion Criteria

• Those with ferromagnetic cerebral aneurysm clips or other intraorbital/intracranial metal; pacemakers, defibrillators, functioning neurostimulator devices, or other implanted non-compatible MRI devices (patients with tissue expanders will not be excluded)
• If previously measured, known LVEF < 50%
• Symptomatic claustrophobia
• Unable to provide informed consent
• At the beginning of the study, pregnant women and women who are breast feeding will not be enrolled.
• Severe pulmonary hypertension
• Within the past 6 months:
  - Acute pulmonary embolus
  - Deep vein thrombosis
• Within the past month:
  - Heart attack
  - Unstable or stable angina (cardiac chest pain)
  - Left main coronary artery disease
  - Symptomatic heart failure
  - Uncontrolled hypertension (SBP > 180 mm Hg or DBP > 120mm Hg)
  - Severe valvular heart disease
  - Uncontrolled metabolic disease (diabetes with fasting BS >300 mg/dl, thyrotoxicosis, myxedema)
  - Aortic aneurism (>45 mm diameter) or aortic dissection
  - Uncontrolled slow or fast heart rhythm causing symptoms or hemodynamic compromise
  - Hypertrophic obstructive cardiomyopathy
- Patient does not understand English

160 Healthy Women Free of Cancer for Comparison

Inclusion Criteria

- Healthy female without known coronary artery disease
- > 18 years old
- Able to hold breath for 10 seconds
- ECOG = 0 or 1
- Able to walk at least 2 blocks without chest pain, dyspnea, shortness of breath or fainting
- Able to exercise on a treadmill or stationary cycle
- No personal history of cancer other than superficial skin cancers
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Has never received chemotherapy, radiation therapy, immunotherapy, or had breast cancer related surgery

Exclusion Criteria

- Inflammatory conditions, such as rheumatoid arthritis, systemic lupus or inflammatory bowel disease
- Overt coronary artery disease or heart failure
  - Those with ferromagnetic cerebral aneurysm clips or other intraorbital/intracranial metal; pacemakers, defibrillators, functioning neurostimulator devices or other implanted non-compatible MRI devices
- If previously measured, known LVEF < 50%
- Symptomatic claustrophobia
- Unable to provide informed consent
  - At the beginning of the study, pregnant women and women who are breast-feeding will not be enrolled.
- Severe pulmonary hypertension
- Within the past 6 months:
  - Acute pulmonary embolus
  - Deep vein thrombosis
- Within the past month:
  - Heart attack
  - Unstable or stable angina (cardiac chest pain)
  - Left main coronary artery disease
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  - Uncontrolled hypertension (SBP > 180 mm Hg or DBP > 120mm Hg)
  - Severe valvular heart disease
    - Uncontrolled metabolic disease (diabetes with fasting BS >300 mg/dl, thyrotoxicosis, myxedema)
  - Aortic aneurism (>45 mm diameter) or aortic dissection
  - Uncontrolled slow or fast heart rhythm causing symptoms or hemodynamic compromise
  - Hypertrophic obstructive cardiomyopathy
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SCHEMA

Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT)

Study Population

840 Stage I-III female breast cancer patients scheduled to receive adjuvant or neo-adjuvant chemo (+ or - radiation therapy) and/or estrogen antagonist aromatase inhibitor therapy and 160 healthy cancer free women for statistical comparisons

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Baseline data collection

MRI, Labs, Demographic, Medical Chart Review*, Current Medications, Physical Assessments, Self-Administered Questionnaires and KCCQ-12, COVID-19 Questionnaire, Neurocognitive Tests, 6-Minute Walk, Disability Measures, SPPB, 45% will undergo a treadmill or stationary bike cardiopulmonary exercise test (CPET), Serum and Plasma Samples*, DNA Lab*

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1 month blood collection

Serum and Plasma Samples*

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3 month data collection

MRI*, Labs, Physical Assessments, Self-Administered Questionnaires, KCCQ-12, Cardiac event assessment, COVID-19 Questionnaire, Neurocognitive Tests, 6-Minute Walk, Disability Measures, SPPB, Serum and Plasma Samples*, DNA Lab*

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12 month data collection

Labs, Physical Assessments, Self-Administered Questionnaires, KCCQ-12, COVID-19 Questionnaire, Cardiac event assessment, Neurocognitive Tests, 6-Minute Walk, Disability Measures, SPPB

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2 year data collection

MRI, Labs, Physical Assessments, Self-Administered Questionnaires and KCCQ-12, COVID-19 Questionnaire, Cardiac event assessment, Neurocognitive Tests, 6-Minute Walk, Disability Measures, SPPB45% will undergo a treadmill or stationary bike cardiopulmonary exercise test (CPET)
Serum and Plasma Samples*

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3-11 yearly data collection

Cardiac event assessment, KCCQ-12

* Indicated for Cancer Treatment Group only

Stratification: equal # of females < 52 years of age vs. ≥ 52 years of age
Anthracycline vs. non-Anthracycline

Study Sample: n=1000

Brief Eligibility Criteria: 840 Females aged ≥ 18 years old who are scheduled to receive adjuvant or neo-adjuvant chemotherapy and/or estrogen antagonist aromatase inhibitor therapy for Stage I-III breast cancer (including inflammatory and newly diagnosed, or locally recurrent but not metastatic breast cancer being treated with curative intent) and 160 healthy cancer free women for statistical comparisons

Study Duration: 24 months per subject with an additional follow-up for 3-9 years (total of 9-11 years)