

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
- 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, non-compatible MRI tissue expanders or breast implants, 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
 - ☐ Symptomatic heart failure
 - ☐ Uncontrolled hypertension (SBP > 180 mm Hg or DBP > 100mm 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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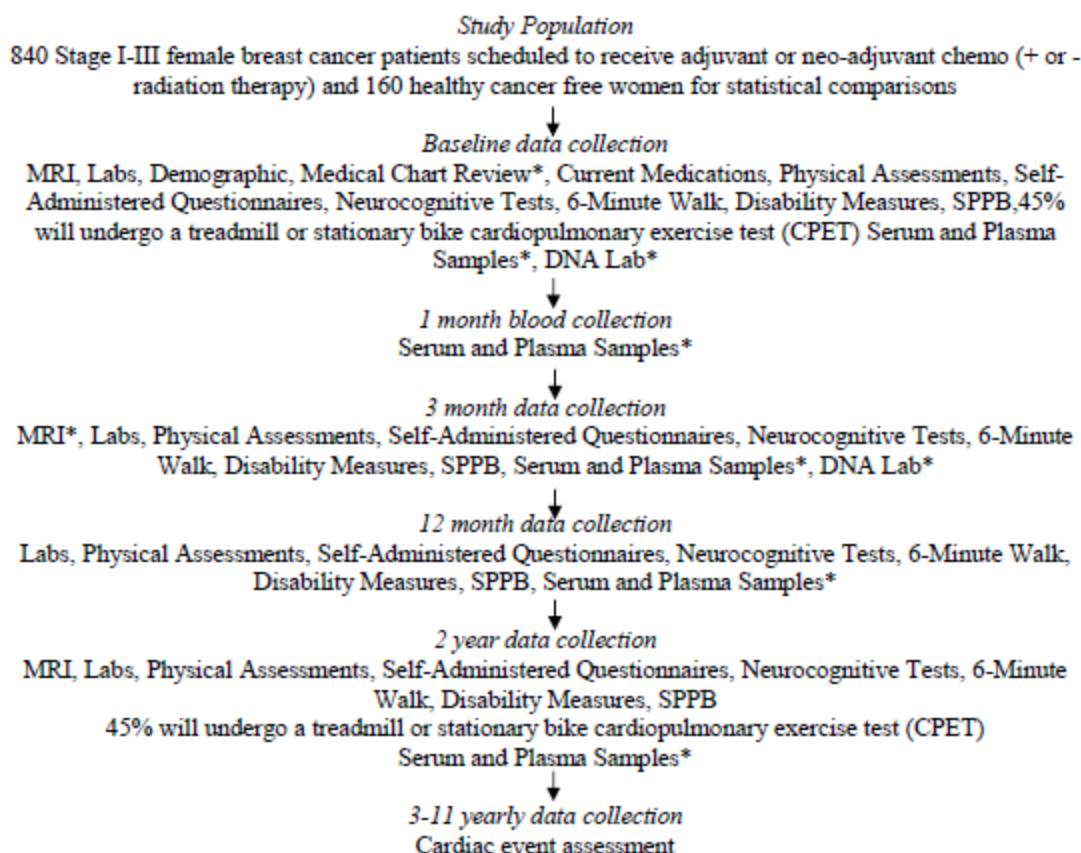
Has never received chemotherapy, radiation therapy, immunotherapy, or had breast cancer related surgery

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
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SCHEMA

Understanding and Predicting Breast Cancer Events after Treatment (UPBEAT)



* Indicated for Chemotherapy 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 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 7-9 years (total of 9-11 years)