Cardiac Outcomes With Near-Complete Estrogen Deprivation

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 55 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria * Women age ≤55 who were premenopausal at the time of breast cancer diagnosis; (Premenopausal is defined as per NCCN criteria). * Planned breast cancer treatment with NCED (near-complete estrogen deprivation) therapy that includes aromatase inhibitor therapy (or SERD) with medically or surgically induced menopause within three (3) months of initiating NCED (HR-positive tumor) or, for the cohorts not receiving NCED therapy, within three (3) months of planned chemotherapy, surgery or radiation. Index date for three months is defined as final date of treatment with chemotherapy, surgery or radiation which ever happens last (HR-negative tumor). Treatment with a Gonadotropin Releasing Hormone (GnRH) agonist for fertility preservation during chemotherapy is allowed and is not considered part of the NCED antineoplastic therapy. * Women with human epidermal growth factor-2 (HER2) negative and women with human epidermal growth factor-2 (HER2) positive breast cancer are eligible. * Treatment with CDK-inhibitor, PARP inhibitor immunotherapy or biologic (non-chemotherapy) agent as part of anti-neoplastic treatment plan is allowed. These agents are not considered chemotherapy. * Treatment with selective-estrogen receptor degrader (SERD) rather than aromatase inhibitor is allowed. * Diagnosed with Stage I-III breast cancer. * ECOG performance status of 0-2 * Patients with concurrent malignancies are eligible as long as therapies and disease course for these are reasonably expected to not impact cardiovascular function. (Examples of eligible malignancies include: papillary/follicular thyroid cancer, basal cell carcinoma of the skin, squamous cell carcinoma of the skin, in-situ and early stage cervical cancers, etc.). * Patients with prior COVID-19 are eligible if they have recovered from the illness and are free of COVID-related symptoms other than allowable persistent symptoms: loss of taste and smell and/or grade 1 fatigue. * Ability to understand and the willingness to sign an IRB-approved informed consent document (either directly or via a legally authorized representative). * The study will allow up to 30% of patients with MRI non-compatible breast expanders recognizing that baseline CMR will be outside of imaging window. Note: Registration of these participants will require study PI approval (Dr. Jordan or Dr. Thomas).

Exclusion Criteria:

* History of allergic reactions attributed to compounds of similar chemical or biologic composition to adenosine * Active wheezing. * Those with contraindications for MRI such as ferromagnetic cerebral aneurysm clips or other intracranial metal, pacemakers, defibrillators, functioning neurostimulator devices or other implanted electronic devices, or some breast expanders. * Uncontrolled intercurrent illness including, but not limited to ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements. * Pregnant women are excluded from this study. Because some methods of birth control are not 100% reliable, a pregnancy test is required, unless the patient has undergone either a bilateral oophorectomy, hysterectomy or both. * Coronary revascularization in the past 6 months or known severe multi-vessel coronary artery disease previously determined to be not amendable to mechanical intervention. * Ongoing, unrelieved symptoms thought to represent cardiac ischemia and requiring immediate cardiac catheterization * Allergy or prior sensitivity to gadolinium or other contrasting agents or their excipients. * Men with breast cancer. * Known chronic renal insufficiency or chronic electrolyte abnormalities as determined by the treating physician.

Conditions & Interventions

Interventions:

DRUG: Adenosine Stress Cardiac Magnetic Resonance Imaging, DIAGNOSTIC_TEST: Electrocardiogram, DIAGNOSTIC_TEST: Computed Tomography Angiogram, OTHER: Laboratory Testing, BEHAVIORAL: Quality of Life Survey

Conditions:

Breast Cancer, Triple Negative Breast Cancer, Cardiovascular Complications

More Information

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Phase: NA

IRB

Number:

System ID: NCT05309655
