Testing the Role of FDG-PET/CT to Predict Response to Therapy Prior to Surgery for HER2-positive Breast Cancer, The DIRECT Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients (all genders) must be \>= 18 years of age. * Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible. * Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. * Patient must have histologically confirmed HER2-positive primary invasive breast carcinoma by American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines that has been determined by local testing. * Patient must have known (either positive or negative) hormone receptor (estrogen receptor \[ER\] or progesterone receptor \[PR\]) status by local testing, per ASCO/CAP guidelines. Patients with either hormone receptor-positive or hormone receptor- negative HER2-positive breast cancer are eligible. * Patient must have American Joint Committee on Cancer (AJCC) 8th Edition stage IIa-IIIc according to anatomic staging table at diagnosis and below criteria. * Patients without nodal involvement (cN0) are eligible if T size \> 2.0 cm (T2-4) * Patients with nodal involvement (cN1-3) are eligible if T2-4 * Patients with clinical T4d are not eligible * Patients with bilateral invasive breast cancers are eligible if both cancers are HER2-positive and at least one meets all protocol eligibility criteria and neither cancer renders the patient ineligible. * Patients with multiple ipsilateral invasive tumors are eligible as long as all tumors are HER2-positive and at least one tumor focus meets all eligibility criteria. Multiple lesions that appear part of the same index tumor do not require additional biopsy/HER2 testing. * Patient must plan to start a standard neoadjuvant pertuzumab (or other biosimilars) based regimen. * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of this imaging intervention are eligible for this trial. * Patients with human immunodeficiency virus (HIV) on effective anti-retroviral therapy with undetectable viral load within 6 months of registration are eligible for this trial. * Patient must be participating in the trial at an institution which has agreed to perform the imaging research studies, completed the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network Cancer Center Group (ECOG-ACRIN) defined PET/CT scanner qualification procedures and received ECOG-ACRIN PET/CT scanner approval. * For patients who completed the baseline (T0) FDG-PET/CT PRIOR to registration, neoadjuvant pertuzumab-based regimen must start after study registration and within 21 days after the T0 scan. * Patients must not have used colony stimulating growth factors within 14 days prior to completing a T0 scan done prior to registration.

Exclusion Criteria:

* Patient must not have any prior treatment for the current breast cancer, including surgery, chemotherapy, hormonal therapy, radiation or experimental therapy. * Patient must not be pregnant or breast-feeding due to the potential harm to an unborn fetus and possible risk for adverse events in nursing infants with the teratogenic effects of FDG in addition to the radiation exposure during PET/CT. All patients of childbearing potential must have a blood test or urine study within 7 days prior to registration to rule out pregnancy. * NOTE: A pregnancy test within 7 days prior to the T0 scan is also required but will only need to be done if a) the T0 scan is completed after study registration and b) if the pregnancy test done prior to registration is completed outside of the 7-day window. A patient of childbearing potential is defined as anyone, regardless of sexual orientation or whether they have undergone tubal ligation, who meets the following criteria: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy; or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months). * Patient must not have any contraindication to FDG-PET/CT imaging which includes routine glucose values \> 200 mg/dL and severe claustrophobia.

Conditions & Interventions

Interventions:
DRUG: Chemotherapy, PROCEDURE: Computed Tomography, OTHER: Fludeoxyglucose F-18, PROCEDURE: Positron Emission Tomography, PROCEDURE: Surgical Procedure

Conditions:
Anatomic Stage II Breast Cancer AJCC v8, Anatomic Stage III Breast Cancer AJCC v8, HER2-Positive Breast Carcinoma, Invasive Breast Carcinoma

More Information

Contact(s): ctrrecruit@vcu.edu
Principal Investigator:
Phase: PHASE2
IRB
Number:
System ID: NCT05710328
