Version 01/04/23

NCI National Clinical Trials Network

EA1211/DIRECT

For Patients with HER2+ Breast Cancer

EA1211 Available Through ECOG-ACRIN Cancer Research Group

Interim FDG-PET/CT for Predicting Response of HER2+ Breast Cancer to Neoadjuvant Therapy (DIRECT)

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age ≥ 18 years (all genders), ECOG PS 0-2,
- Must have histologically confirmed HER2+ primary invasive breast carcinoma by ASCO/CAP guidelines (determined by local testing)
- Must have known ER/PR status by local testing (ASCO/CAP guidelines); patients with hormone receptor-positive or hormone receptor-negative HER2+ breast cancer are eligible
- Must be Stage IIa-IIIc (AJCC 8th ed.):
  - ◊ Patients without nodal involvement (cN0) are eligible if T size > 2.0cm (T2-4)
  - ◊ Patients with nodal involvement (cN1-3) are eligible if T2-4
  - ◊ Patients with clinical T4d are not eligible
- Patients with bilateral HER2+ invasive breast cancers or multiple ipsilateral invasive tumors can be eligible; see protocol for details
- Must not have had any prior treatment for the current breast cancer (surgery, chemo, hormonal therapy, radiation, or experimental therapy)
- Must plan to start a standard neoadjuvant pertuzumab (or other biosimilar)-based regimen
- Patients with a prior/concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety/efficacy of this imaging intervention are eligible
- Patients with HIV are permitted per protocol
- Must not be pregnant/breast-feeding
- Must not have any contraindication to FDG-PET/CT imaging (i.e., routine glucose values > 200 mg/dL, severe claustrophobia)
- Must be participating at a site that agreed to perform the imaging research studies, completed the EA-defined PET/CT scanner qualification and received EA approval (see protocol for details)

Treatment Plan

See Section 5.0 for Complete Study Plan Details

- Patients will undergo FDG-PET/CT imaging at baseline (T0) and on day 15 (+ 7 days) of cycle 1 (T1) of the selected neoadjuvant pertuzumab-based systemic regimen
  - ◊ T0 PET/CT scan can be done prior to or after registration and both must meet the parameters of the EA1211 Imaging Manual and Section 7.5
    - ⇒ After: must be completed within 21 days of registration, prior to initiating the systemic treatment, which must start within 21 days of T0 scan (note: if T0 is M1/stage IV, patient will come off study)
    - ⇒ Before: systemic treatment must start after registration and within 21 days of T0 scan
- T1 (cycle 1 day 15 [+ 7 days]) FDG-PET/CT scan must be completed prior to start of day 1 cycle 2 treatment
  - ◊ Patients must not use long-acting colony stimulating growth factors within 14 days prior to completing T0 and T1 FDG-PET/CT scans
  - ◊ The use of daily filgrastim is discouraged and must be completed within 72 hours prior to T1 FDG-PET/CT
- Standard of care (SOC) neoadjuvant therapy options (as recommended by the treating physician):
  - ◊ Docetaxel or paclitaxel, herceptin, pertuzumab (THP) x 12 weeks
  - ◊ Docetaxel or paclitaxel, carboplatin, herceptin, pertuzumab (TCHP) x 18 weeks
  - ◊ Note: if a paclitaxel/docetaxel allergy is experienced, or the patient needs to avoid steroid medications, nab-paclitaxel can be substituted
  - ◊ In patients with evidence of disease progression during neoadjuvant therapy, additional pre-surgical therapy should be given at the discretion of the treating oncologist
- After neoadjuvant therapy, patient will undergo SOC surgery per treating physician

Study Chair:
Heather Jacene, MD

Study Co-Chair:
Roisin Connolly, MD

Patient Enrollment

All Sites: Oncology Patient Enrollment Network (OPEN) https://open.ctsu.org

Protocol Information

ECOG-ACRIN Operations-Boston: 857-504-2900, http://ecog-acrin.org (Member Login)

Please Enroll Your Eligible Patients!

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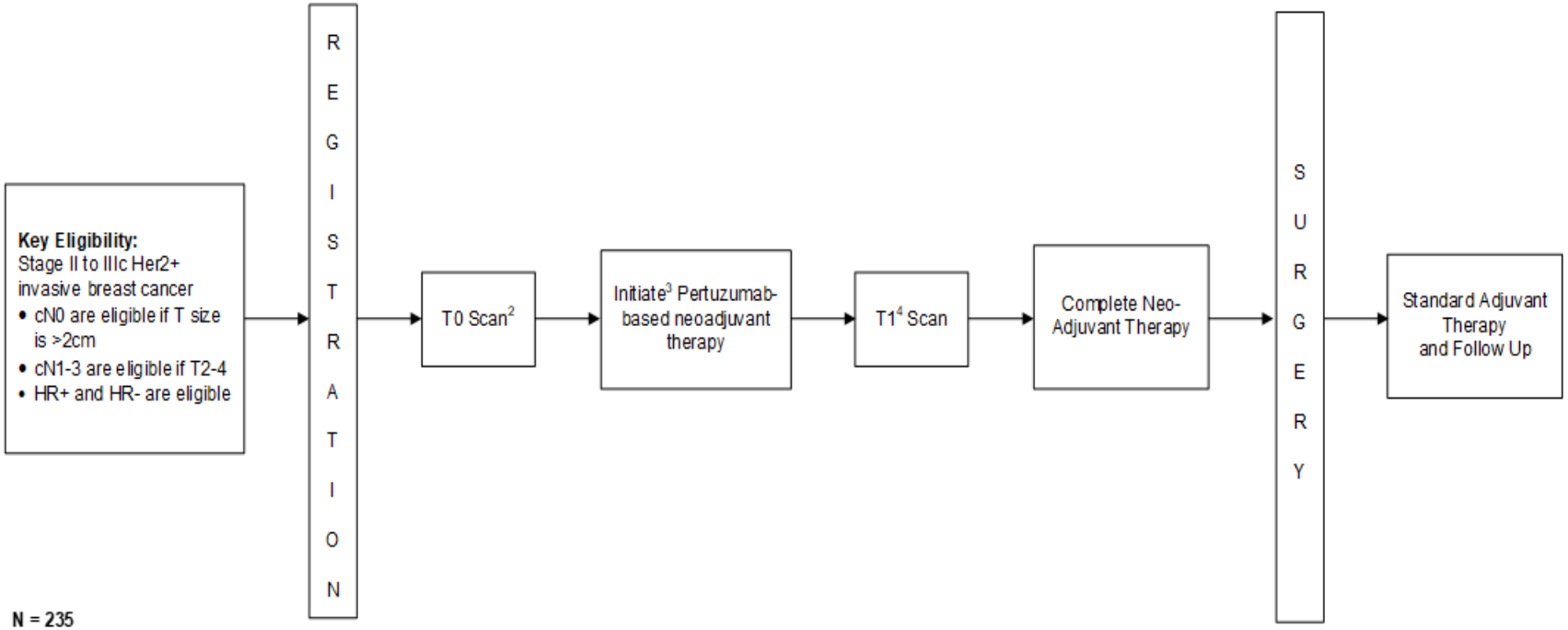
ECOG-ACRIN cancer research group

EA1211

Schema



1. Screening tests outlined in Section 7.1 must be completed within 28 days prior to registration.
2. Some patients may have a qualifying PET scan completed prior to registration, see Section 7. Neoadjuvant therapy should begin after study registration and completion of T0.
3. Neoadjuvant therapy should start within 21 days after the T0 scan is completed. Therapy can include Docetaxel or Paclitaxel, Herceptin, Pertuzumab (or biosimilars) (THP) x 12 weeks (every three weeks for 4 cycles) OR Docetaxel, Carboplatin, Herceptin, Pertuzumab (or biosimilars) (TCHP) x 18 weeks (every three weeks for 6 cycles). See Section 5.3.
4. T1 scan to be completed on Day 15 (+7 days) of Cycle 1, should be completed prior to start of treatment on Cycle 2 Day 1 and should be completed on same scanner as T0.
5. Follow-up will be a minimum of three years or maximum of 5 years from patient registration. See the study parameters table for frequency.