

EA1183/FEATURE

For Patients with Bone-dominant Metastatic Breast Cancer

EA1183 Available Through ECOG-ACRIN Cancer Research Group

FDG PET to Assess Therapeutic Response in Patients with Bone-dominant Metastatic Breast Cancer, FEATURE

Patient Population

See Section 3.0 for Complete Eligibility Details

- Age \geq 18 years, ECOG PS \leq 2, life expectancy estimated at \geq 24 weeks
- Must have radiographically confirmed metastatic breast cancer with histologic confirmation of either metastatic or primary tumor biopsy by local assessment that is HR+ (ASCO/CAP) and with known HER2 status
- Must have radiologically confirmed bone-dominant (BD)/bone-only (BO) disease (defined per protocol) confirmed by scans within 60 days of registration
- No patients with RECIST 1.1 measurable lesions in viscera, active CNS, leptomeningeal carcinomatous or pleural/periosteal disease (note: prior CNS metastases permitted per protocol)
- No contraindication to FDG-PET imaging (see protocol)
- Must have 1 of the following systemic therapies (note, the use of bone-stabilizing agents is permitted):
 - ◇ Plan to receive either 1st, 2nd or 3rd line endocrine therapy for metastatic breast cancer (i.e., SERMs, aromatase inhibitors, and/or fulvestrant that may be combined with FDA-approved biologic agents)
 - ◇ Plan to receive chemotherapy per NCCN/institutional standard
 - ◇ Plan to receive HER2-targeted therapy per ASCO/NCCN/institutional guidelines (for patients with HER2+ disease)
- Must not have received colony stimulating growth factor within 14 days prior to completing the T0 FDG-PET/CT scan
- Must meet institutional guidelines for renal function for MRI and CT scanning
- No patients who received greater than 3 lines of cytotoxic chemotherapy for metastatic breast cancer
- No known additional malignancy that is progressing or requires active treatment (exceptions per protocol)
- Institution is EA PET/CT qualified/approved

Treatment Plan

See Section 5.0 for Complete Study Plan Details

- **T0 (baseline FDG-PET/CT) scan** can be performed prior to patient registration, but the scan must meet all imaging parameters outlined in the Imaging Manual; patients completing the scan post study registration, must complete it within 28 days of registration
- **Systemic therapy** is to start within 21 days after T0 scan and must start after patient registration, no exceptions. If the patient cannot start systemic therapy in this timeframe, then the T0 scan should be completed after the patient is registered to the trial and treatment can begin after the T0 scan
- **Optional 4-week FDG-PET/CT scan:** For patients that consent, this PET/CT should be completed 4-week (\pm 7 days) from systemic treatment initiation
- **The T1 scan** should be completed 12 weeks (\pm 14 days) from systemic treatment initiation
- **Patients with diabetes** should be reviewed by the referring provider to determine if the patient has blood glucose levels routinely equal or under 200 mg/dL to allow repeated scans to be performed
- **Patients must not use colony stimulating growth factor** within 14 days prior to completing T0, T1, and the optional 4-week FDG-PET/CT scan
- All patients will be followed for response until progression, even if non-protocol therapy is initiated, and for survival for a minimum of three years after the last patient is registered and a maximum of five years

Study Chair:
Jennifer Specht, MD

Study Co-Chair:
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Patient Enrollment

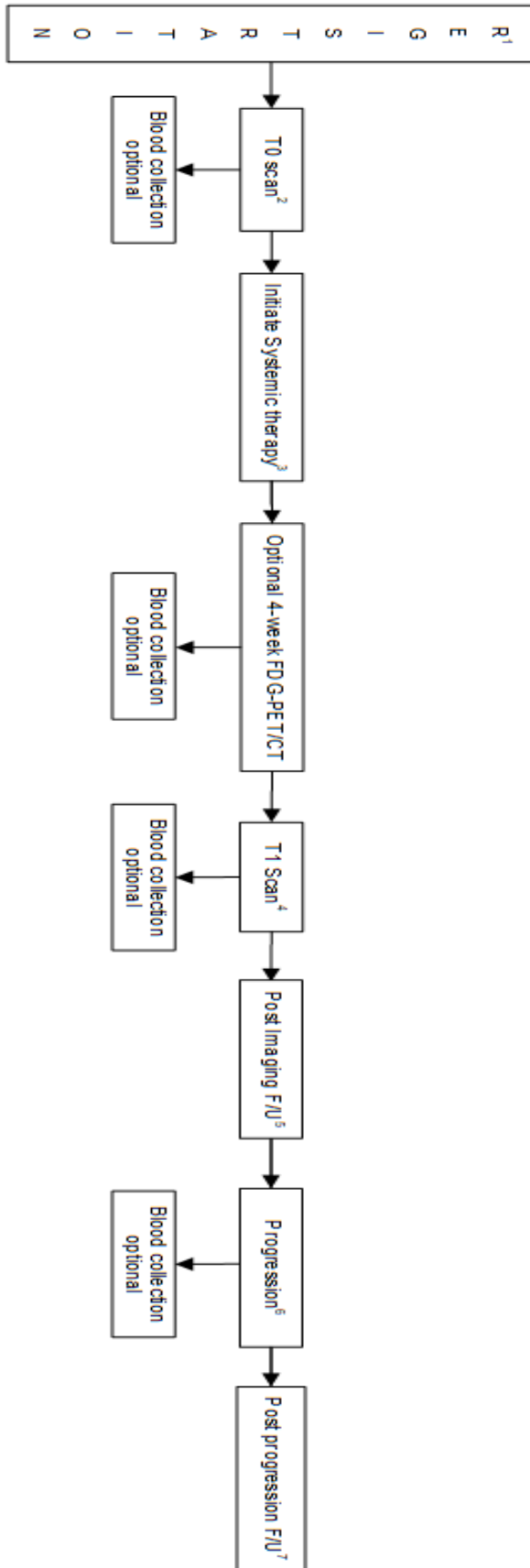
All Sites: Oncology Patient Enrollment Network (OPEN) <https://open.ctsu.org>

Protocol Information

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

Please Enroll Your Eligible Patients!

EA1183



1. Screening tests outlined in Section 8.1 to be completed prior to registration.
2. Some patients may have a qualification scan done prior to registration, see Sections 3 and 7.4. Systemic treatment should begin after patient registration and after completion of T0.
3. Therapy to begin within 21 days of T0 scan. Note: If T0 scan completed prior to registration, systemic therapy must be initiated within 21 days of T0 scan. FDG-PET/CT scan can be completed again on study if necessary to make this requirement. Note: If T0 scan was completed prior to registration, systemic therapy must still be initiated within 21 days of the T0 scan (systemic therapy to start after patient registration).
4. T1 scan to be completed 12 weeks (+/- 14 days) from start of therapy.
5. SOC imaging and clinical follow-up every 12 weeks (+/- 14 days) for 4 cycles, and then done every 24 weeks (+/- 28 days) until disease progression or until completion of follow-up.
6. Recommended FDG-PET/CT at progression prior to starting new therapy.
7. Patients will be followed every six months to assess survival status and skeletal related events for a minimum of three years after the last patient is registered and a maximum of five years.