Cancer Research Consortium of West Michigan
P: 616.391.1230 | 800.336.6299 | www.crcwm.org

FAST FACTS

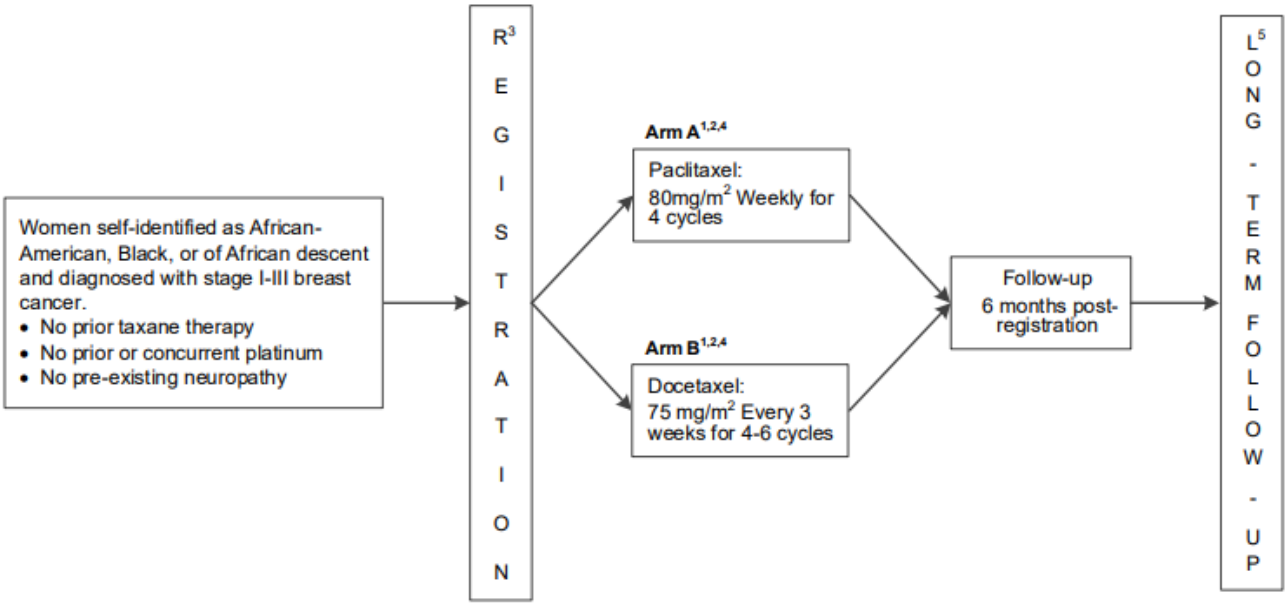
EAZ171 - Prospective validation trial of taxane therapy (docetaxel or weekly paclitaxel) and risk of chemotherapy-induced peripheral neuropathy in African American women

Eligibility Criteria

1. Patients must be women with a known stage I-III invasive breast cancer diagnosis.
2. Patients must be age ≥ 18 years.
3. Patients must be capable and willing to provide informed consent.
4. Patients must have plans to receive either neoadjuvant or adjuvant:
   - **a.** Every 3-week docetaxel x 4-6 cycles
   - b. Weekly paclitaxel x 4 cycles

   NOTE: Recommended therapies for various therapy regimens are outlined in Section 5.1 based on ER/PR/HER2 and nodal status. Where there are options, the treating physician will choose a regimen best fitted for that patient. If the physician does not feel any of the regimens are the best fit for the patient, the patient should not be enrolled. Physicians will also document why a regimen was felt to be inappropriate when an option. Patients who have already started the anthracycline portion of their therapy are eligible assuming they have not yet begun the taxane portion and assuming they will be receiving one of the regimens deemed appropriate for her disease setting as outlined in Section 5.1.
5. Patients must self-identify their race as black, African American, or of African descent. Patients may be of any ethnicity.
6. Patients must not have received prior taxane or prior/concurrent platinum therapy.
7. Patients must not have received neoadjuvant anti-HER2 therapy.
8. Patients with a history of other cancers are eligible if they have not received prior taxane or platinum or vinca alkaloid therapy.
9. Patients must not have pre-existing peripheral neuropathy.
10. ECOG Performance status 0-1
11. Patients must not have a total bilirubin > ULN or AST and/or ALT above 1.5 times the ULN concomitant with alkaline phosphatase above 2.5 times the ULN.
12. Patients must not be pregnant or lactating.
    All females of childbearing potential must have a blood test or urine study within 2 weeks prior to registration to rule out pregnancy.
    A female of childbearing potential is any woman, 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 for at least 24 consecutive months (i.e., has had menses at any time in the preceding 24 consecutive months).
    Date of blood test or urine study: _____
13. Women of childbearing potential must be strongly advised to use an accepted and effective method of contraception or to abstain from sexual intercourse for the duration of their participation in the study.

Schema



Accrual = 240

1 cycle = 21 days

1. Peripheral blood samples are to be collected and submitted following registration, prior to treatment for the mandatory protocol-defined laboratory research studies.
2. PROs are to be administered per Section 5.6. PROs for administration are: Functional Assessment of Cancer Therapy Gynecological Oncology Group Neurotoxicity (FACT/GOG-NTX) PROMIS Physical Function v2.0 Short Form 10a, Comprehensive Score for Financial Toxicity (COST), five items from the Alliance Patient Questionnaire for Clinical Trials In Oncology, PRO CTCAE items, and CIPN20.
3. Treatment arm will be determined at the discretion of the treating investigator.
4. Concurrent therapy is to be administered per Sections 5.1 and 5.4.
5. Every 3 months if patient is < 2 years from their date of registration, every 6 months if patient is 2-5 years from their date of registration. Patients will be followed for 5 years from their date of registration.