Cancer Research for the Ozarks

Version 01/30/14 (Upd. #2)

A011106

For Postmenopausal Women with Clinical Stage II/III Estrogen Receptor Positive Breast Cancer

A011106 Available Through the CTSU

ALTernate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study

Patient Population

See Section 4.0 for Complete Eligibility Details

- Must be postmenopausal verified by: Post bilateral surgical oophorectomy; or no spontaneous menses ≥ 1 year; or no menses for <1 year with FSH and estradiol levels in postmenopausal range per institutional standards.
- Must have pathologically confirmed invasive breast cancer diagnosed by core needle biopsy.
- Must have clinical T2-T4c, any N, M0 invasive breast cancer (as defined by AJCC 7th edition) with goal of complete surgical removal of the tumor in the breast and the lymph node.
- The extent of disease must be a palpable solitary lesion that is ≥ 2.0 cm at its greatest diameter.
- Must have ER+ invasive breast cancer with an Allred score of 6, 7, or 8 by institutional standards. If Allred score is not reported on the diagnostic pathology report, ER+ in > 66% cells is eligible (if ≤ 66%, staining intensity is needed to calculate Allred score to determine eligibility).
- Must have HER2 negative invasive breast cancer defined as 0 or 1+ by IHC OR with FISH ratio <2 if IHC 2+ by local institutional standard protocol.
- Must agree to provide the required research biopsies at baseline, week 4 and at surgery for integral and integrated biomarkers and correlative studies.
- Must not have a history of invasive breast cancer; or contralateral DCIS; or inflammatory breast cancer as defined by the protocol.
- Must not have prior excisional biopsy of this breast cancer or surgical axillary staging procedure prior to entry (except for FNA or core needle biopsy of axillary node).
- Must not have clinical or radiographical evidence of metastatic disease (exception: isolated ipsilateral supraclavicular node involvement is permitted).
- Must not have had HRT of any type, megestrol acetate, or raloxifene within one week prior to registration; must not have received prior treatment for this cancer.

Treatment Plan

See Section 8.0 for Complete Treatment Details

Notes:

- All patients will initially be randomized to hormonal therapy in Arm I, II, or III.
- Hormone therapy cycles are 28 days long.
- Patients who are determined by biopsy to have Ki67 > 10% at Week 4 or 12 will discontinue hormonal therapy and receive neoadjuvant chemotherapy as described below.

Arm I:

- Anastrozole 1mg PO QD for 6 cycles

Arm II:

- Fulvestrant 500mg IM
  - Days 1 and 15 of Cycle 1 only
  - Day 1 of Cycles 2-6

Arm III:

- Anastrozole 1mg PO QD for 6 cycles
- Fulvestrant 500mg IM
  - Days 1 and 15 of Cycle 1 only
  - Day 1 of Cycles 2-6

Surgery: Should be performed between Days 15-28 of Cycle 6 for each arm.

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Neoadjuvant Chemotherapy Group:

Paclitaxel 80 mg/m^2 on Days 1, 8, 15 and 22 x 3 cycles or other standard regimen at physician's discretion. Followed by surgery.

Number of Participants: 2820

Alliance Protocol Chair: Cynthia X. Ma, MD, PhD

Patient Enrollment

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

Protocol Information

CTSU Help Desk 1-888-823-5923, CTSUcontact@westat.com, www.ctsu.org

Please Enroll Your Eligible Patients!

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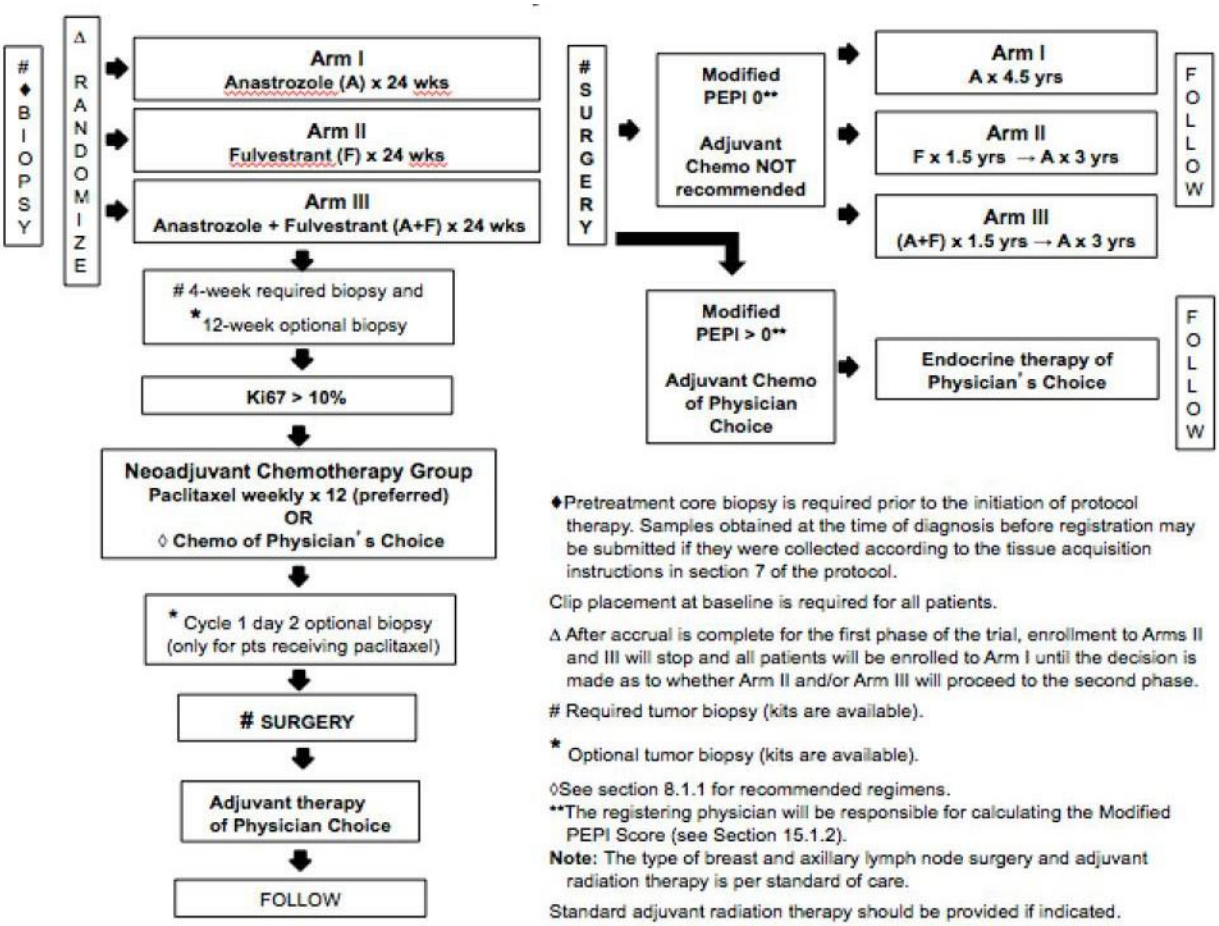
Schema



♦Pretreatment core biopsy is required prior to the initiation of protocol therapy. Samples obtained at the time of diagnosis before registration may be submitted if they were collected according to the tissue acquisition instructions in section 7 of the protocol.

Clip placement at baseline is required for all patients.

Δ After accrual is complete for the first phase of the trial, enrollment to Arms II and III will stop and all patients will be enrolled to Arm I until the decision is made as to whether Arm II and/or Arm III will proceed to the second phase.

Required tumor biopsy (kits are available).

* Optional tumor biopsy (kits are available).

◊See section 8.1.1 for recommended regimens.

**The registering physician will be responsible for calculating the Modified PEPI Score (see Section 15.1.2).

Note: The type of breast and axillary lymph node surgery and adjuvant radiation therapy is per standard of care.

Standard adjuvant radiation therapy should be provided if indicated.