Testing Low Dose Tamoxifen for Invasive Breast Cancer, the (LoTam) Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Unilateral invasive adenocarcinoma of the breast that is histologically confirmed * Invasive breast cancer is estrogen receptor positive in ≥ 10% of cells * HER2 negative by current American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines * The patient must have a multigene assay with a low-risk score, including any of the following (if more than one genomic assay was obtained, both are required to be low-risk): * Oncotype DX recurrence score ≤ 25 * Mamma Print low risk * Prosigna risk of recurrence ≤ 40 * Tumor size must be ≤ 3 cm by pathologic evaluation * Adequate surgical removal of all clinically evident disease in the breast with either breast conserving surgery or mastectomy. Negative margins on final pathology are required. Additional excisions may be performed to obtain clear margins before registration * No clinical (cN1, cN2, cN3) or pathologic (pN1mi, pN1, pN2, or pN3) evidence of lymph node involvement on either needle biopsy or surgical lymph node assessment. Patients with pN0(i+) or pN0 (mol+) are eligible * Surgical axillary staging (sentinel lymph node biopsy ± axillary lymph node dissection) is completed according to physician discretion * For patients with negative preoperative axillary ultrasonography, clinicians may selectively choose to forego surgical axillary staging. Ipsilateral axillary ultrasound showing no lymph node involvement with no evidence of lymphadenopathy or suspicious thickening is required in this scenario * No pathological tumor size \> 3 cm or pT4 * No definitive clinical or radiologic evidence of metastatic disease * No palpable or radiographically suspicious axillary, supraclavicular, infraclavicular, or internal mammary lymph nodes, unless there is histologic confirmation that these lymph nodes are negative for tumor * No suspicious microcalcifications, densities, or palpable abnormalities in the ipsilateral or contralateral breast, unless biopsied and found to be benign * An interval of no more than 20 weeks between the date of surgery and the date of registration * Must have had a bilateral mammogram or MRI within 6 months prior to registration * Must be intending to take endocrine therapy for at least 5 years duration * No prior treatment with endocrine therapy or chemotherapy for the currently diagnosed breast cancer prior to registration. (Short course endocrine therapy of ≤ 6 weeks duration is acceptable after core biopsy and before surgery, if genomic testing is assessed on the biopsy core and meets eligibility requirements for a low-risk score.) * No use of oral hormone replacement therapy within 7 days prior to registration * Age ≥ 18 years * Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 * Postmenopausal status confirmed as: * No spontaneous menses ≥ 1 year * No menses for \< 1 year with follicle stimulating hormone (FSH) and estradiol levels within a postmenopausal range according to institutional standards * Previous bilateral surgical oophorectomy * None of the following conditions: * Abnormal or dysfunctional uterine bleeding within 1 year prior to study enrollment * Any patient with known atypia or endometrial pathology that the opinion of the treating investigator would place the patient at undue risk of endometrial cancer with tamoxifen. * Any patient with a known hypercoagulable state that in the opinion of the treating investigator would put the patient at undue risk of venous thromboembolism with tamoxifen * No history of breast or thoracic radiotherapy for any previous condition. Patients may complete radiotherapy for the currently diagnosed breast cancer prior to registering for the study. In this scenario, registration must be completed within 12 weeks of completing breast radiotherapy * No previous history of ipsilateral invasive breast cancer or ipsilateral ductal carcinoma in situ (DCIS), regardless of the disease-free interval * No synchronous or previous contralateral invasive or non-invasive breast cancer * 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 the investigational regimen are eligible for this trial * No patients with premenopausal status * No current treatment with any endocrine therapy for breast cancer prevention or osteoporosis, including raloxifene, tamoxifen, or other selective estrogen receptor modulator. Patients intending to continue oral hormone replacement are not eligible * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial

Conditions & Interventions

Interventions:

DRUG: Anastrozole, DRUG: Letrozole, DRUG: Exemestane, DRUG: Tamoxifen, PROCEDURE: Mammogram, PROCEDURE: Magnetic Resonance Imaging, BIOLOGICAL: Dual X-ray Absorptiometry, PROCEDURE: Biospecimen Collection, OTHER: Questionnaire Administration

Conditions:

Anatomic Stage 0 Breast Cancer AJCC v8, Anatomic Stage 1 Breast Cancer AJCC v8, Anatomic Stage IIA Breast Cancer AJCC v8, Estrogen Receptor-Positive Breast Carcinoma, HER2-Negative Breast Carcinoma

More Information

Contact(s): Jack Beranek - breastprotocols@alliancenctn.org

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06671912