

Evaluating the Addition of Adjuvant Chemotherapy to Ovarian Function Suppression Plus Endocrine Therapy in Premenopausal Patients With pN0-1, ER-Positive/HER2-Negative Breast Cancer and an Oncotype Recurrence Score Less Than or Equal to 25

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 60 years old
This study is NOT accepting healthy
Healthy Volunteers: volunteers

Inclusion Criteria:

* A patient cannot be considered eligible for this study unless ALL of the following conditions are met. * The patient or a legally authorized representative must provide study-specific informed consent prior to pre-entry and, for patients treated in the U.S., authorization permitting release of personal health information. * Female patients must be greater than or equal to 18 years of age. * Patients must be premenopausal (evidence of functioning ovaries) at the time of pre-entry. For study purposes, premenopausal is defined as: * Age 50 years or under with spontaneous menses within 12 months; or * Age greater than 50-60 years with spontaneous menses within 12 months plus follicle-stimulating hormone (FSH) and estradiol levels in the premenopausal range; or * Patients with amenorrhea due to IUD or prior uterine ablation must have FSH and estradiol levels in the premenopausal range; or * Patients with prior hysterectomy must have FSH and estradiol levels in the premenopausal range. * The patient must have an ECOG performance status of less than or equal to 2 (or Karnofsky greater than or equal to 60%). * Patients may have ipsilateral or contralateral synchronous breast cancer if the highest stage tumor meets entry criteria, and the other sites of disease would not require chemotherapy or HER2-directed therapy. * Patients may have multicentric or multifocal breast cancer if the highest stage tumor meets entry criteria, and the other sites of disease would not require chemotherapy or HER2-directed therapy. * Patient may have undergone a total mastectomy, skin-sparing mastectomy, nipple-sparing mastectomy, or a lumpectomy. * For patients who undergo a lumpectomy, the margins of the resected specimen or re-excision must be histologically free of invasive tumor and DCIS (ductal carcinoma in situ) with no ink on tumor as determined by the local pathologist. If pathologic examination demonstrates tumor at the line of resection, additional excisions may be performed to obtain clear margins. Positive posterior margin is allowed if surgeon deems no further resection possible. (Patients with margins positive for LCIS (lobular carcinoma in situ) are eligible without additional resection.) * For patients who undergo mastectomy, the margins must be free of residual gross tumor. (Patients with microscopic positive margins are eligible if post-mastectomy RT (radiation therapy) of the chest wall will be administered.) * Patient must have undergone axillary staging with sentinel node biopsy (SNB), targeted axillary dissection (TAD), or axillary lymph node dissection (ALND). * The following staging criteria must be met postoperatively according to AJCC 8th edition criteria: * By pathologic evaluation, primary tumor must be pT1-3. (If N0, must be T1c or higher.) * By pathologic evaluation, ipsilateral nodes must be pN0 or pN1 (pN1mi, pN1a, pN1b, pN1c). * Patients with positive isolated tumor cells (ITCs) in axillary nodes will be considered N0 for eligibility purposes. * Patients with micrometastatic nodal involvement (0.2-2 mm) will be considered N1. * Oncotype DX RS (recurrence score) requirements*: * If node-negative: * Oncotype DX RS must be RS 21-25, or * Oncotype DX RS must be 16-20 and disease must be high clinical risk, defined as: low histologic grade with primary tumor size greater than 3 cm, intermediate histologic grade with primary tumor size greater than 2 cm, or high histologic grade with primary tumor size greater than 1 cm. * If 1-3 nodes involved: * Oncotype DX RS must be less than 26. * Patients with a "Low Risk" or "MP1" MammaPrint (a genomic test that analyzes the activity of certain genes in early-stage breast cancer) result must have eligibility assessed with an Oncotype DX RS at pre-entry (see Section 3.1). Blocks or unstained slides must be sent to the Genomic Health centralized laboratory for testing at no cost to these patients. If MammaPrint High Risk or MP2, these patients are not eligible. * The tumor must be ER and/or PgR-positive (progesterone receptor) by current ASCO/CAP guidelines based on local testing results. Patients with greater than or equal to 1% ER and/or PgR staining by IHC will be classified as positive. * The tumor must be HER2-negative by current ASCO/CAP (American Society of Clinical Oncology/College of American Pathologists) guidelines based on local testing results. * The interval between the last surgery for breast cancer (including re-excision of margins) and pre-entry must be no more than 16 weeks. * Short course of endocrine therapy of less than 6 weeks duration before pre-entry is acceptable either as neoadjuvant or adjuvant therapy. An Oncotype DX RS must be performed on core biopsy specimen obtained prior to initiation of neoadjuvant endocrine therapy if received. * Patients with a prior or concurrent non-breast 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. This would include prior cancers treated with curative intent. * HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial. * Radiation therapy should be used according to standard guidelines; the intended radiation therapy should be declared prior to pre-entry.

Exclusion Criteria:

* • Definitive clinical or radiologic evidence of metastatic disease. * pT4 (pathological state) tumors, including inflammatory breast cancer. * History of ipsilateral or contralateral invasive breast cancer. (Patients with synchronous and/or previous DCIS or LCIS are eligible.) * If prior ipsilateral DCIS was treated with lumpectomy and XRT (ionizing radiation therapy), a mastectomy must have been performed for the current cancer. * Life expectancy of less than 10 years due to co-morbid conditions in the opinion of the investigator. Known results from most recent lab studies obtained as part of routine care prior to study entry showing ANY of the following values: * ANC (absolute neutrophil count) less than 1200/mm3; * Platelet count less than 100,000/mm3; * Hemoglobin less than 10 g/dL; * Total bilirubin greater than ULN (upper limit of normal) for the lab or greater than 1.5 x ULN for patients who have a bilirubin elevation due to Gilbert's disease or similar syndrome involving slow conjugation of bilirubin; * AST(aspartate aminotransferase)(SGOT)/ALT (alanine transminase)(SGPT): greater than 3 x institutional ULN; * Renal function of GFR (glomerular filtration rate) less than 30 mL/min/1.73m2. * Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better. * Non-epithelial breast malignancies such as sarcoma or lymphoma. * Any treatment with radiation therapy, chemotherapy, or biotherapy administered for the currently diagnosed breast cancer prior to pre-entry. (Patients with prior ET of more than 6 weeks duration for treatment of this cancer are not eligible.) Prior tamoxifen given for breast cancer prevention is allowed. Prior AI or GnRH for fertility preservation is allowed. * Hormonally based contraceptive measures must be discontinued prior to pre-entry (including progestin/progesterone IUDs). * Patients with evidence of chronic hepatitis B virus (HBV) infection are ineligible unless the HBV viral load is undetectable on suppressive therapy. Patients with a history of hepatitis C virus (HCV) infection are ineligible unless they have been treated and cured or have an undetectable HCV viral load if still on active therapy. * Pregnancy or lactation at the time of pre-entry. (Note: Pregnancy testing according to institutional standards for women of childbearing potential must be performed within 2 weeks prior to pre-entry.) * Other conditions that, in the opinion of the investigator, would preclude the patient from meeting the study requirements or interfere with interpretation of study results.

Conditions & Interventions

Interventions:

DRUG: Ovarian Function Suppression + Aromatase Inhibitor, DRUG: Adjuvant Chemotherapy + Ovarian Function Suppression

Conditions:

Breast Cancer

More Information

Contact(s): Director Regulatory Affairs - langerj@nrgoncology.org

Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT05879926

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