Protocol Title: Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

Target Population: Stage II and Stage IIIA Breast Cancer

Summary: To evaluate whether radiation to the undissected axilla and regional lymph nodes just as sufficient as axillary lymph node dissection with radiation to the regional lymph nodes in terms of invasive breast cancer recurrence-free interval in patients with positive SLN(s) after completion of neoadjuvant chemotherapy.

Key Inclusion Criteria:
- Clinical Stage T1-3 N1 M0 Breast Cancer at diagnosis.
- All patients must have had an axillary ultrasound with Fine Needle Aspiration (FNA) or Core Needle Biopsy of axillary lymph nodes documenting axillary metastasis prior to, or at most 14 Days after starting, neoadjuvant chemotherapy.
- Patients must have had ER and PR Status, as well as HER2 status by IHC or FISH evaluated on diagnostic core biopsy prior to start of neoadjuvant chemotherapy.
- Patients must have completed all planned chemotherapy prior to surgery.
  - Patients must have completed at least 4 cycles of neoadjuvant chemotherapy consisting of an Anthracycline and/or Taxane-based regimen without evidence of disease progression in the Breast or the Lymph Nodes.
- Patients with HER-2 Positive tumors must have received neoadjuvant Trastuzumab or Trastuzumab + Pertuzumab or other approved anti-HER-2 therapy.
- All patients must have a clinically negative axilla.
- Intra-Operative Registration/Randomization Criteria:
  - Will sample 1-6 sentinel / non-sentinel nodes during surgery, and at least 1 must have metastasis >0.2mm identified on intra-operative pathology assessment.
- Post-Operative Registration/Randomization Criteria:
  - When ALND was not performed on initial surgery (a maximum of 8 nodes identified post-operatively in pathology report), and a positive lymph node was identified in post-surgical pathology report.

Key Exclusion Criteria:
- For those patients who also undergo contralateral breast surgery, if invasive disease is found in the contralateral breast, the patient is not eligible for registration/randomization.
- No neoadjuvant endocrine therapy, radiation therapy, or ipsilateral SLN/axillary surgery/excision prior to or during chemotherapy.
- No prior history of ipsilateral Invasive Breast Cancer or DCIS or concurrent contralateral Invasive Breast Cancer.
  - Note: Contralateral benign or in situ disease is acceptable.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT01901094

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