Protocol Title: Phase III Randomized Trial of Hypofractionated Post Mastectomy Radiation with Breast Reconstruction

Target Population: Stage II, IIA, IIB, or IIIA Breast Cancer with ductal, lobular, mammary, medullary, or tubular histologies

Summary: This randomized phase III trial studies how well hypofractionated radiation therapy works in preventing recurrence in patients with Stage IIa-IIIa Breast Cancer who have undergone mastectomy.

Key Eligibility Criteria:
- Histologically confirmed invasive carcinoma of the breast of any of the following histologies (ductal, lobular, mammary, medullary, or tubular).
  - NOTE: In-situ disease alone is NOT allowed.
- Final Stage IIa - IIIa (pathologic stage T0N1a-2a, T1N1a-2a, T2N1a-2a, T3N0-2a, all M0 status).
  - Pathological stage for all patients not receiving neoadjuvant chemotherapy.
  - Higher of the clinical or pathological T and N stage, if receiving neoadjuvant chemotherapy.
  - Patients with pathological N0 at the time of mastectomy are only eligible if biopsy-proven clinically N1 or N2 disease is documented prior to induction chemotherapy.
- No prior radiation therapy to the chest, neck or axilla.
- No prior history of ipsilateral breast cancer (invasive disease or ductal breast carcinoma in situ [DCIS]).
  - Lobular carcinoma in situ (LCIS) and benign breast disease is allowed.
- No history of prior or concurrent contralateral invasive breast cancer.
  - Benign breast disease, LCIS, or DCIS of contralateral breast is allowed.
- No active collagen vascular diseases, such as: systemic lupus erythematos, scleroderma, or dermatomyositis.
- Negative inked histologic margins from mastectomy pathology (no invasive cells at margin).
- No significant post mastectomy complications requiring an unplanned re-operation or admission for IV antibiotics.
  - Re-operation for margins evaluation, nodal completion and routine reconstruction is acceptable.
- Radiation oncologist intends to treat all target volumes and respect all normal tissues in accordance with the dosimetric constraints described (simulation before registration recommended).
- Radiation oncologist is planning to treat regional lymph nodes including internal mammary nodes and meet acceptable protocol dosimetric requirements.
- Radiation oncologist is NOT planning to utilize a chest wall/scar boost.
- Patient must have undergone immediate reconstruction at the time of mastectomy or be planning to undergo reconstruction within 8 Months after radiation.
- No co-existing medical conditions with life expectancy < 5 Years.
- No other malignancy within 5 Years of registration with the exception of basal cell or squamous cell carcinoma of the skin treated with local resection only or carcinoma in situ of the cervix.
- ECOG (Zubrod) Performance Status 0-1.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03414970