Alliance A011202: A 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 Receiving Neoadjuvant Chemotherapy

Judy Boughey MD, Bruce Haffty MD, Thomas Buchholz MD, W. Fraser Symmans MD, Kelly Hunt MD, Jane Armer, PhD, RN, Vera Suman PhD

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Rationale

The rapid accrual to ACOSOG Z1071 demonstrated a high level of interest in the question of nodal staging in patients with node positive breast cancer treated with neoadjuvant chemotherapy, both from the physicians treating the patients and the patients themselves. After the results of Z1071 were released the care of these patients changed and SLN surgery is increasingly used to stage residual disease after chemotherapy.

Axillary lymph node dissection has been the standard for women with residual nodal involvement. Recent trials have shown axillary radiation may be as good as axillary dissection in local control of axillary disease, however this question has not been assessed in the post-neoadjuvant chemotherapy setting.

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Objective

Primary
To evaluate whether radiation to the undissected axilla and regional lymph nodes is not inferior to axillary lymph node dissection with radiation to the regional lymph nodes but not to the dissected axilla in terms of: invasive breast cancer recurrence-free interval

Secondary
The incidence of invasive loco-regional recurrence (secondary)

Additional secondary objectives:
- Examine distribution of Residual Cancer Burden scores in each treatment arm
- Estimate overall survival in each treatment arm

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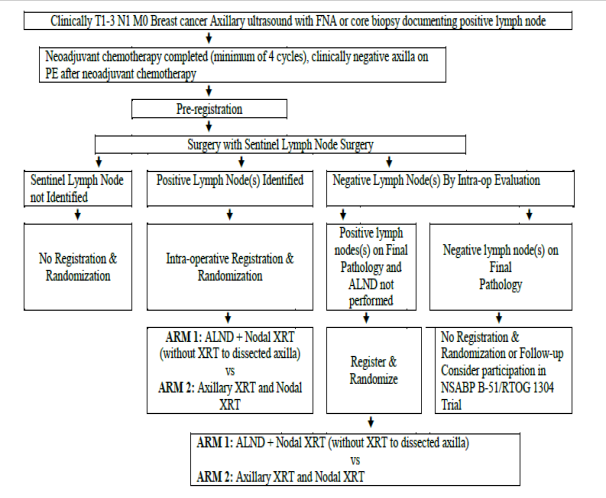
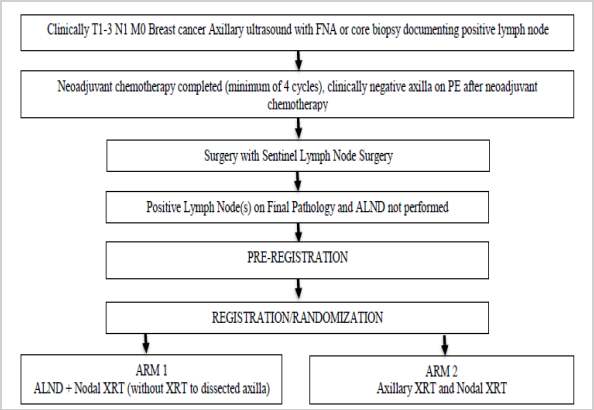
Study Schema

Patients who pre-register prior to SLN surgery



Patients who pre-register after surgery (where SLN was performed but ALND was not)



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Treatment Plan

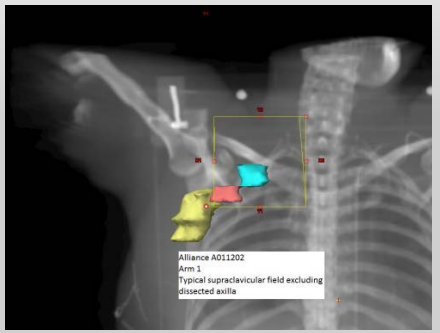
Treatment of the Axilla

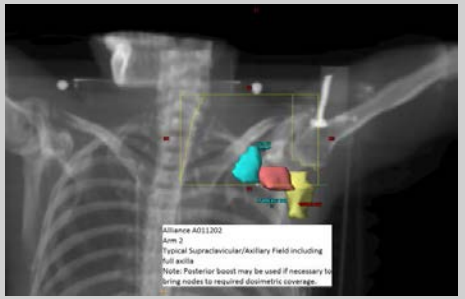
Arm 1

- ALND – removal of level I and II LNs
- Radiation to the breast (for breast conserving patients) or chest wall (for mastectomy patients) and regional nodal irradiation to level III LNs and supraclavicular fossa.

Arm 2

- No ALND
- Radiation to the breast (for breast conserving patients) or chest wall (for mastectomy patients) and regional nodal irradiation to level **I, II,** III LNs and supraclavicular fossa.





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Key Eligibility Criteria

Inclusion Criteria

- Female or male ≥ 18 years old
- cT1-3, N1, M0 clinical stage
- Axillary FNA or core biopsy documenting nodal disease at presentation
- Invasive breast cancer
- ER, PR, Her2 testing on breast tumor core biopsy
- Completed at least 4 cycles of neoadjuvant chemo
- Her2 positive disease must have received anti-Her2 therapy
- Negative axilla on physical exam after completion of neoadjuvant chemotherapy (NAC) – no bulky adenopathy
- Surgery performed ≤56 days after NAC completion

Exclusion Criteria

- Inflammatory breast cancer or any cT4
- Clinical N2 or N3 disease at presentation
- Neoadjuvant radiation
- Previous ipsilateral axillary surgery
- SLN surgery or excisional biopsy of axilla prior to or during NAC
- History of or concurrent contralateral invasive breast cancer
- Pregnant or lactating

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