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 NEOADJUVANT CHEMOTHERAPY

Schema for patients who pre-register prior to SLN surgery:

Clinically T1-3 N1 M0 Breast cancer Axillary ultrasound with FNA or core biopsy documenting positive lymph node

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Neoadjuvant chemotherapy completed (minimum of 4 cycles), clinically negative axilla on PE after neoadjuvant chemotherapy

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Pre-registration

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Sentinel Lymph Node not Identified

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No Registration & Randomization

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Positive Lymph Node(s) Identified

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Intra-operative Registration & Randomization

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Negative Lymph Node(s) By Intra-op Evaluation

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Positive lymph nodes(s) on Final Pathology and ALND not performed

↓

ARM 1: ALND + Nodal XRT (without XRT to dissected axilla)

vs

ARM 2: Axillary XRT and Nodal XRT

↓

Register & Randomize

↓

Negative lymph node(s) on Final Pathology

↓

ARM 1: ALND + Nodal XRT (without XRT to dissected axilla)

vs

ARM 2: Axillary XRT and Nodal XRT

Schema for patients who pre-register AFTER surgery* (where SLN surgery was performed but ALND was NOT performed):

 Clinically T1-3 N1 M0 Breast cancer Axillary ultrasound with FNA or core biopsy documenting positive lymph node

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Neoadjuvant chemotherapy completed (minimum of 4 cycles), clinically negative axilla on PE after neoadjuvant chemotherapy

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Surgery with Sentinel Lymph Node Surgery

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Positive Lymph Node(s) on Final Pathology and ALND not performed

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PRE-REGISTRATION

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REGISTRATION/RANDOMIZATION

↓

ARM 1

ALND + Nodal XRT (without XRT to dissected axilla)

↓

ARM 2

Axillary XRT and Nodal XRT

* Patients who are pre-registered after SLN surgery are NOT eligible to enroll onto the Arm Lymphedema Companion Study (A011281-ST1)

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