

CTSU Z1071: A Phase II Study Evaluating the Role of Sentinel Lymph Node Surgery and Axillary Lymph Node Dissection Following Preoperative Chemotherapy in Women with Node Positive Breast Cancer (T0-4, N1-2, M0) at Initial Diagnosis

Fast Facts

Eligibility Criteria

A patient will be eligible for inclusion in this study only if **ALL** of the following criteria apply:

1. >18 years old
2. ECOG/Zubrod Performance Status 0-1
3. Female. NOTE: Men are excluded from this study because the number of men with breast cancer is insufficient to provide a statistical basis for assessment of effects in this subpopulation of people with breast cancer.
4. Histologic diagnosis of invasive breast cancer, clinical stage T0-4 N1-2 M0 (excluding inflammatory breast cancer).
5. FNA biopsy or core needle biopsy of an axillary node documenting nodal disease at time of diagnosis and prior to preoperative chemotherapy.
6. Preoperative chemotherapy must be completed or planned for patient. NOTE: Patients enrolling on studies involving preoperative chemotherapy (through cooperative groups or institutional studies) may be eligible for this study, provided sentinel node surgery prior to preoperative chemotherapy was not required in the other studies.
7. No prior ipsilateral axillary surgery, such as excisional biopsy of lymph node(s) or treatment of hidradenitis.
8. No prior SLN surgery/excisional lymph node biopsy for pathological confirmation of axillary status.

Pre-Study Parameters – to be completed prior to chemotherapy initiation

1. History and physical including weight and performance status
2. Axillary ultrasound (as part of a routine breast US)
3. FNA or core biopsy of axillary lymph node
4. Breast biopsy