

**Z0011:**

# **A randomized trial of axillary node dissection in women with clinical T1 or T2 N0 M0 breast cancer who have a positive sentinel node**

**ClinicalTrials.gov Identifier:** NCT00003855

## **Study Background**

**Trial Design:** This is a phase III randomized trial to determine the effectiveness of removing lymph nodes in the armpit in treating women who have stage I or stage IIA breast cancer. Women with clinical stage T1 or T2 N0 M0 breast cancer who are found to have a sentinel node (SN) containing metastatic breast cancer through sentinel lymph node dissection (SLND) with breast conserving therapy (BCT), as documented on frozen section, touch prep, or permanent section evaluation by hematoxylin and eosin (H&E) staining, will be randomized to one of two Arms:

- **Arm 1:** Completion axillary lymph node dissection (ALND), followed by whole breast radiation therapy and, if indicated, systemic adjuvant therapy
- **Arm 2:** No immediate additional axillary surgery or axillary-specific radiation, followed by whole breast radiation therapy and, if indicated, systemic adjuvant therapy.

### **Objectives:**

#### Primary

- *Long term:* To assess whether overall survival for patients randomized to Arm 2 (no immediate ALND) is essentially equivalent to (or better than) than that for patients assigned to Arm 1 (completion ALND).
- *Short term:* To quantify and compare the surgical morbidities associated with SLND plus ALND versus SLND alone.

### **Stratification Factors:**

- Age:  $\leq 50$  or  $> 50$ .
- Estrogen Receptor (ER) status: positive or negative.
- Tumor size:  $\leq 1$  cm,  $> 1$  cm or  $\leq 2$ cm, or  $>2$  cm.

<b>Study History:</b>	1/31/2002	Activation Date
	12/15/2004	Close Date
	Aug 2007	Primary Completion Date
	Feb 2011	Study Completion Date

## **Publication Information**

**Analysis Type:** Primary Endpoint Analysis

**PubMed ID:** 21304082

**Citation:** Giuliano AE, Hunt KK, Ballman KV, Beitsch PD, Whitworth PW, Blumencranz PW, Leitch AM, Saha S, McCall LM, Morrow M. Axillary Dissection vs No Axillary Dissection in Women With Invasive Breast Cancer and Sentinel Node MetastasisA Randomized Clinical Trial. *JAMA*. 2011;305(6):569-575. doi:10.1001/jama.2011.90

**Associated** NCT00003855\_D1\_(efficacy)

**Datasets:**

## Dataset Information

**Dataset Name:** NCT00003855\_D1\_(efficacy)

**Description:** The NCT00003855\_D1\_(efficacy) contains all manuscript data on treated patients only (n=856).

### NCT00003855 D1 (efficacy) Data Dictionary\*

\*Throughout the dictionary NA refers to any value that was not collected or otherwise missing.

Variable Description	Variable Name	Code	Notes
Patient identifier	patref		If data is submitted to NCTN Navigator for this trial, this ID will be able to tie clinical data with NCTN submission.
Patient age in years at registration	age		Participants who are 90 years old or older were categorized as >=90 in the code
Arm	arm	1=ALND 2=No ALND	Missing values indicate the data was not available and not reported as part of the manuscript.
Arm Label	armlabel	ALND No ALND	
Clinical T stage	stage	1 = T1 2 = T2	
Local recurrence indicator	local	1=yes, 0=Patient was not identified as having local recurrence.	
Regional recurrence indicator	regional	1=yes, 0=Patient was not identified as having regional recurrence.	
Distant recurrence indicator	distant	1=yes, 0=Patient was not identified as having distant recurrence.	
Vital Status indicator	fu_stat	1=dead 0=alive	
Recurrence indicator	pg_stat	1=recurrence 0=no recurrence	
New primary indicator	nprim_stat	1=new primary 0=no new primary	
Days between registration and date of last known	fu_time	Numeric	

alive or date of death			
Years between registration and date of last known alive or date of death	fu_yrs	Numeric	
Days between registration and date of recurrence or last recurrence assessment	pg_time		
Disease Free Survival indicator	dfs_stat	1=recurred or died 0=not recurred or dead	
Days between registration and recurrence or death	dfs_time	Numeric	
Number of sentinel nodes removed	sln		
Number of positive SLN	possln		
Number of axillary nodes removed	aln		
Number of positive ALN	posaln		
Total lymph nodes removed	tln		
Primary tumor-breast	PTBRST	1=Right 2=Left	
Pathologic tumor size	PATHTSZ		As measured in centimeters (cm).  Note: Due to data cleaning efforts, a minor discrepancy was found reported in Table 1 in the publication.
Primary tumor type: ductal	PTTYP1	1=Infiltrating ductal, 0=Participant did not report having Infiltrating ductal disease.	
Primary tumor type: lobular	PTTYP2	1=Infiltrating lobular, 0=Participant did not report having Infiltrating lobular disease.	
Primary tumor type: other	PTTYP3	1=Other tumor type, 0=Participant did not report having other tumor type.	
Margin tumor free	MARGTUM	1=Yes 2=No	

Estrogen receptor status	estrogen1	1=Negative 2=Positive	
Progesterone receptor status	progest1	1=Negative 2=Positive	
Lymphovascular invasion	lvi1	1=Yes 2=No	
Primary tumor type	hist	1=Infiltrating ductal 2=Mixed ductal and lobular 3=Infiltrating lobular 4=Other	
SLN ID technique used	SNTECH	1=Blue dye only 2=Radiopharmaceutical only 3=Both NA=Unknown or not Done	
Matted axillary nodes	MNODE	1=Yes 2=No NA indicates data not collected	
Gross extracapsular invasion	GECINV	1=Yes 2=No, NA indicates data not collected	
Lymphoscintigram Not Done	LSND	1=Not done 0=Lymphoscintigram Done	
Lymphoscintigram:axillary	LSRES1	1=yes 0=no	
Lymphoscintigram: other	LSRES2	1=yes 0=no	
Gamma counting not done	IGCND	1=Not done 0=Gamma counting done	
IGC Result: axillary	IGCRES1	1=yes 0=no	
IGC result: other	IGCRES2	1=yes 0=no	
Number of SLN found by pathologist	PTOTSN		NA means data was not collected.
Number of SLN positive by pathologist	POSSN		NA means data was not collected.
Sentinel node involved (any positive SLN)	SNINV	1=Yes 2=No	
Metastatic tumor size (in axilla)	tumorsz1	1=Micro ( $\leq 2$ mm) 2=Macro ( $> 2$ mm)	
Modified Bloom-Richardson score	mbrsc1	1=I 2=II 3=III	
Whole breast irradiation done	wbi3	1=yes 0=no	

Adjuvant radiation therapy given	rt	1=yes 0=no	
Adjuvant hormonal therapy given	hormone	1=yes 0=no	
Adjuvant chemo therapy given	chemo	1=yes 0=no	
Adjuvant chemo or hormonal therapy given	adjther	1=yes 0=no	
Tumor type	hist1	1=Infiltrating ductal 2=Infiltrating lobular 3=Other	
Total number of positive SLNs and ALNs	totposln	0=0 1=1 2=2 3=3 4= $\geq$ 4	Note: A discrepancy from the manuscript is one patient in the SLND group moved from the 1 positive node to the 4 or more positive nodes category.  The variable only includes where posln and posaln are both non-missing for the ALND group.