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

Study Chair: Armando Giuliano, MD

Activation Date: 4/30/1999  Closure Date: 12/15/2004
Accrual Goal: 1900 patients  Final Accrual: 891 patients
Current Amendment: A8  Participating Groups: ACOSOG  NCCTG  NSABP  CTSU

Diagram:

Breast Cancer Clinical T1 or T2, N0, M0

BCT, SLND with Positive SLN

Eligible & Consent?

register

Randomize

Arm 1: ALND

Breast Radiation Therapy
Systemic Adjuvant Therapy

Arm 2: No further surgery

Follow
Objectives

Women with clinical stage T1 or T2 N0 M0 breast cancer will undergo sentinel lymph node dissection (SLND) with breast conserving therapy (BCT). Women who are found to have a sentinel node containing metastatic breast cancer, 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).

**Arm 2**: No immediate additional axillary surgery or axillary-specific radiation.

Women in both Arms will have whole breast radiation therapy and systemic adjuvant therapy.

Women who participate in this study (Z0011) may also be registered to study Z0010. However, this is not required for participation in Z0011.

Primary Objectives:

**Long term**: To assess whether overall survival for patients randomized to Arm 2 (no immediate ALND) is essentially equivalent to (or better 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.

Summary Statement

From May 17, 1999 through December 15, 2004, 891 patients were accrued from 111 Physician Groups, 445 on Arm 1 and 446 on Arm 2. On March 1, 2004, this trial was activated through the CTSU, and one patient was enrolled through this mechanism. The study was closed due to slow accrual and a lower than expected event rate on both arms. All patients enrolled on this trial continue to be followed per protocol. Please see the June 2005 Report of Studies for information on accrual, demographics, and adverse events.

An abstract titled “ACOSOG Z0011: A randomized trial of axillary node dissection in women with clinical T1-2 N0 M0 breast cancer who have a positive sentinel node” by Armando Giuliano et al was presented at the 2010 American Society of Clinical Oncology meeting.

The primary endpoint data have matured sufficiently and a manuscript reporting the primary aim is under development.

The following manuscripts from this trial have been published:

