ACOSOG

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Title: ACOSOG Z1031: A randomized phase III trial comparing 16–18 weeks of neoadjuvant exemestane (25mg daily), letrozole (2.5mg), or anastrozole (1mg) in postmenopausal women with clinical stages II and III estrogen receptor positive breast cancer.

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Summary:

- Opened in March 2006
- Target accrual: 375 patients

Primary Objective:

To determine whether anastrozole, exemestane or letrozole administered for 16–18 weeks as neoadjuvant endocrine treatment for postmenopausal patients with stage II or III ER + breast cancer should be chosen as the aromatase inhibitor of a future study that will compare a neoadjuvant aromatase inhibitor treatment with neoadjuvant chemotherapy.

Secondary Objectives:

- To compare the neoadjuvant treatment regimens relative to the rates of improvement in surgical outcome defined as follows:

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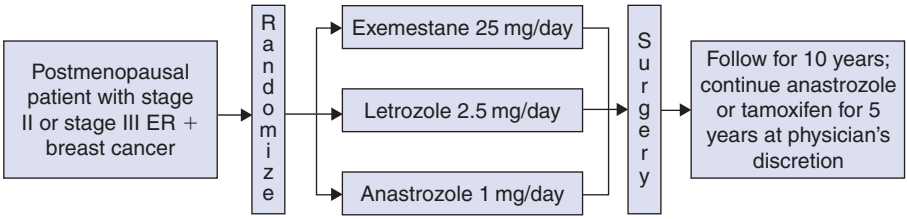
  - For T4 a, b, c tumors: mastectomy with primary skin closure and negative surgical margins.
  - For T3 and T2 tumors classified as requiring mastectomy at baseline: breast conserving surgery with negative final margins.
  - For T2 tumors classified as potential candidates for breast conservation: wide excision at first attempt.
- To compare the radiological response rates (mammography and ultrasound by central radiological analysis) between these three neoadjuvant treatment regimens.
- To compare the relative safety of the neoadjuvant treatment regimens in terms of reported adverse events.

Scheme:

Z1031: A randomized phase III trial comparing 16–18 weeks of neoadjuvant exemestane (25 mg daily), letrozole (2.5 mg daily) or anastrozole (1 mg daily), in postmenopausal women with clinical stage II or III estrogen receptor postive breast cancer



Update: Total accrual: 21 patients as of 25 September, 2006.

Related Publications: None available

Topics:

- Aromatase inhibitors
- Breast conservative treatment
- Hormonal therapy
- Hormone receptor positive breast cancer
- Postmenopausal patients

Keywords: Neoadjuvant endocrine therapy, estrogen receptor positive breast cancer

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Title: ACOSOG Z0010: A prognostic study of sentinel node and bone marrow micrometastases in women with clinical T1 or T2 N0 M0 breast cancer.

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Summary:

- Opened in May 1999
- Target accrual: 5300 patients

Primary and Secondary Objectives:

- To estimate the prevalence and to evaluate the prognostic significance of sentinel node micrometastases detected by immunohistochemistry (IHC).
- To estimate the prevalence and to evaluate the prognostic significance of bone marrow micrometastasis detected by immunocytochemistry (ICC).
- To evaluate the hazard rate for regional recurrence in women whose sentinel nodes are negative by hematoxylin and eosin (H&E) staining.
- To provide a mechanism for identifying women whose sentinel nodes contain metastases detected by H&E so that these women can be considered as candidates for Study Z0011.

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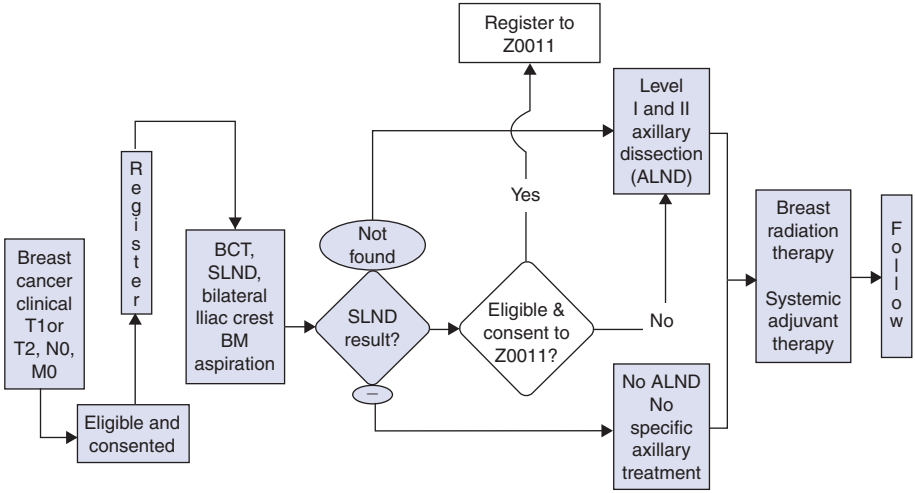
Scheme:



Update:

- Study closed in May 2003 with 5539 patients.
- Five-year results have not yet been published.

Related Publications:

Leitch AM, *et al*. Patterns of participation and successful patient recruitment to ACOSOG Z0010, a phase II trial for patients with early stage breast cancer. *Am J Surg* 2005; 190(4): 539–542.

Posther KE, *et al*. Sentinel node skills verification and surgeon performance: data from a multicenter clinical trial for early stage breast cancer. *Ann Surgery* 2005; 242(4): 593–599; discussion 599–602.

Wilke LG, *et al*. Surgical complications associated with sentinel lymph node biopsy: results from a prospective international cooperative group trial. *Ann Surg Oncol* 2006; 13(4): 491–500.

Topics:

- Bone marrow micrometastasis
- Breast conservative treatment
- Loco-regional relapse
- Node negative breast cancer
- Prognostic factors
- Sentinel node micrometastasis
- Sentinel node resection

Keywords: Sentinel lymph node biopsy, bone marrow micrometastases, immunohistochemistry

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Title: 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.

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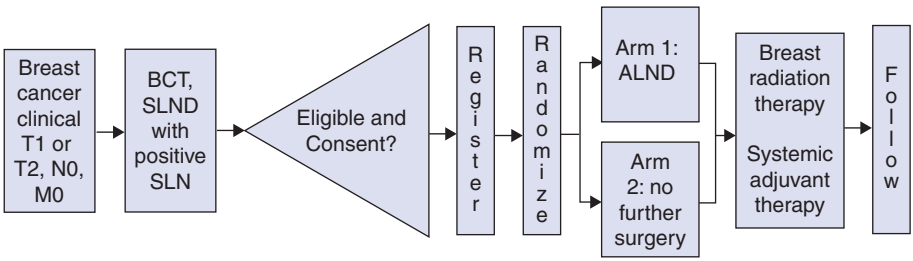
Summary:

- Opened in May 1999
- Target accrual: 1900 patients

Objectives:

- *Long term:* To assess whether overall survival for patients randomized to Arm 2 (no immediate axillary lymph node dissection, 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 sentinel lymph node dissection (SLND) plus ALND *versus* SLND alone.

Scheme:



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Update:

- The study closed in 15 December 2004 secondary to slow accrual with 891 patients.

Related Publications:

Lucci A, *et al*. Surgical complications associated with sentinel lymph node dissection (SLND) plus axillary lymph node dissection, *versus* SLND alone in the American College of Surgeons Oncology Group (ACOSOG) Trial Z0011. *Ann Surg Oncol* 2006; 13(2): 4.

Topics:

- Axillary lymph node dissection
- Breast conservative treatment
- Loco-regional relapse
- Node positive breast cancer
- Sentinel node micrometastasis
- Sentinel node resection

Keywords: Sentinel node biopsy, surgical morbidity, lymphedema

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