

ACS surgical trial accrual campaign: Get involved, make a difference

The American College of Surgeons Oncology Group (ACOSOG) leadership met January 12–14 to discuss strategies to ensure successful grant renewal in 2006. Key deliverables for 2006 are (1) patient accrual to ACOSOG trials and (2) published reports from completed trials. ACOSOG leadership is promoting a campaign to enhance patient recruitment to ACOSOG and ACOSOG-endorsed trials. We need your help.

ACOSOG is dedicated to involving ACS Fellows in the research agenda of the National Cancer Institute (NCI). We will work closely with the ACS, Commission on Cancer, and Cancer Liaison Program to recruit surgeons to enroll patients in clinical trials.

Each month we will deliver the information you need to help

engage you in this important enterprise. In past columns, we have provided a short primer on joining a cooperative group and provided lists of clinical trials available to surgeons. In the coming months, we will deliver in-depth descriptions of important new surgical trials and help surgeons with points on how to participate. Tomorrow's practice comes from today's research. Get involved and make a difference!

This month's featured clinical trial is **Z1031: Neoadjuvant Aromatase Inhibitors in Breast Cancers**.

• *What is the study?* This study is a phase III trial that compares three aromatase inhibitors in the preoperative setting. Tumor tissue and blood samples will be collected for correlative science studies and sur-

gical, radiologic, and pathologic endpoints will be compared. (See box on next page.)

• *Who can participate?* Participation is open to postmenopausal women with stage II or III estrogen receptor (ER) positive breast cancer.

• *Why is this study being done?* Chemotherapy is sometimes given before surgery to shrink breast tumors to allow breast-conserving surgery or to improve the chance that the tumor can be removed adequately by mastectomy. Recent studies have shown that estrogen-lowering drugs called "aromatase inhibitors" are an effective and less toxic alternative for postmenopausal women with hormone-dependent tumors. This study is designed to further investigate this treatment approach.

ACOSOG-led and ACOSOG-endorsed (CTSUS*) protocols open to accrual

For a more complete list, please visit the ACOSOG Web site at www.acosog.org

Breast	Z1031	Neoadjuvant aromatase inhibitors in breast cancer
	NSABP B-35*	Anastrozole with tamoxifen in patients with DCIS undergoing lumpectomy with radiation
	NSABP B-39*	Whole breast radiation vs. partial breast radiation for breast cancer
Head and Neck	Z0360	Sentinel lymph node mapping and lymphadenectomy for oral cavity SCCa
Gastrointestinal	Z6041	Local excision and neoadjuvant chemoradiation for early rectal cancer
Sarcoma	Z9001	Adjuvant ST1571 vs. placebo following resection of primary GIST
	Z9031	Preoperative radiation plus surgery vs. surgery alone for RPS
Thoracic	Z4031	Proteomic analysis for detection of non-small cell lung cancer
	Z4032	Brachytherapy and sublobar resection in non-small cell lung cancer

Z1031: Neoadjuvant Aromatase Inhibitors in Breast Cancers

Patients will be randomized at the start of the study.



Patients will receive:

→ **Group 1: Exemestane**

Patients randomized to Group 1 will take 1 tablet (25 mg) of exemestane once per day for 16 weeks, OR

→ **Group 2: Letrozole**

Patients randomized to Group 2 will take 1 tablet (2.5 mg) of letrozole once per day for 16 weeks, OR

→ **Group 3: Anastrozole**

Patients randomized to Group 3 will take 1 tablet (1 mg) of anastrozole once per day for 16 weeks



Patients will have surgery.



Patients will see their physician 30 days after completing the study drug and the outcome will be recorded every two years for 10 years. The physician may recommend that patients continue taking an estrogen-lowering drug or tamoxifen for five or more years, and patients may also receive other therapies such as chemoradiation or radiation therapy.

The primary purpose of the Z1031 study is to find out which aromatase inhibitor is the best one to use for future ACOSOG

studies. All three aromatase inhibitors under investigation have been shown to shrink breast cancers and to improve the chances

of breast conservation. Patients will be treated with 16 weeks of daily oral doses of either exemestane, letrozole, or anastrozole. Another aim is to develop new tests that can be used to predict which patient will do well with this form of treatment. For this reason, patient consent will be requested for extra tumor biopsies and for access to tumor samples taken at surgery.

• *How many surgeons get involved?* Surgeons who treat women with breast cancer should go to www.acosog.org for information on membership. For more information, call the NCI's Cancer Information Service at 800/4-CANCER (800/422-6237), or TTY 800/332-8615, or visit the Web site at <http://www.cancer.gov>.

Information can also be found in the December 2005 *Bulletin* (ACOSOG news: Cooperative group membership: An online three-step process. *Bull Am Coll Surg.* 2005;90(12):40-41).

Trauma and Critical Care–Point/Counterpoint to be held in June

The 25th Annual Conference, Trauma and Critical Care–Point/Counterpoint, convenes in Colonial Williamsburg, VA, June 5–7.

The theme of this year's meeting is "What's New in Trauma/Critical Care" and includes sessions on resuscitation beyond the basics; an exciting video session on technical advances; difficult case management panels (including the challenging and

fun *Survivor* game for faculty); a thorough look at liver injuries and their operative management; a review of penetrating trauma to the chest, abdomen, neck, and central nervous system; pelvic fractures from the standpoint of the surgeon, orthopaedist, and interventionalist; and an in-depth look at results of recent multicenter studies and how they have changed our approach to pa-

tient care. There are breakfast and lunch sessions on disaster preparation and analysis and on system problems–system solutions, including Level I overload, the role of the Level IIIs, telemedicine in rural trauma care, and economics.

This program is directed to the surgeon and surgical specialist but should also be of interest to practitioners of critical care and emergency medicine.