

CALGB 70305: A Randomized Study to Prevent Lymphedema in Women Treated For Breast Cancer

FAST FACTS

ELIGIBILITY CRITERIA

STEP ONE ELIGIBILITY

1. Newly diagnosed with Stage I-III Cancer of the Female Breast.
2. No prior history of carcinoma in situ, LCIS, DCIS, or invasive cancer. Patients with a history of other invasive malignancies are eligible as long as they have completed treatment and are 5 years post-diagnosis. Patients with basal cell and squamous cell cancer of the skin are eligible.
3. Patients scheduled to receive any type of radiation therapy to the breast or axilla are eligible; however, they must be registered to this study with pre-surgery measures (see section 7.1) taken prior to receiving neoadjuvant therapy.
4. Patients scheduled to receive neoadjuvant chemotherapy are also eligible; however, they must be registered to this study with pre-surgery measurements taken prior to receiving neoadjuvant therapy.
5. Patients receiving no neoadjuvant therapy are eligible.
6. May be enrolled on other treatment trials. However, patients enrolled on surgery trials where only one treatment arm is full axillary node dissection are not eligible. Note: Patients on Z1071 are eligible. Patients concurrently enrolled on Z1071 may also participate in the Z1071 lymphedema sub-study.
7. No documented cardiac conduction disturbances, unstable angina, dementia, or any other chronic disease which, in the opinion of the treating physician, significantly increases mortality over the next 2 years.
8. No diagnosed lymphedema.
9. In order to be properly fitted for the elastic sleeve, eligible patients must have arm measurements for axilla, elbow, and wrist that fall within the ranges for one of the six sleeve sizes listed in section 3.1.7.
10. Not currently homebound or dependent upon a walker or wheelchair for mobility.
11. Able to participate in a mild exercise program.
12. Willing to return to the study site for the duration of the study (18 months).
13. Age \geq 18 years.

STEP TWO ELIGIBILITY

1. Sentinel (SND) of Full axillary node dissection (AND) (no minimum of nodes required)
2. Patients with double mastectomy, axillary node dissection and/or radiation on both arms are ineligible. Patients who undergo these treatments (i.e., surgery and/or radiation) on the contralateral arm after registration to Step 2 are still eligible to remain in the study; however, it should be documented appropriately on form C-1628 at the conclusion of study participation.
3. Patients who received sentinel axillary node dissection only are not eligible.
4. Patients with double mastectomy and axillary node dissection and/or radiation on both arms are ineligible.

PRE-SURGERY VISIT (ARMS A AND B):

1. Pre-surgery measures will be obtained by the institutional nurse for all patients registered to Step 1 (i.e., those patients scheduled for an axillary or sentinel node dissection)
2. Questionnaires to be completed by the participant, with the assistance of the nurses, if necessary, include measures of lymphedema knowledge; health-related quality of life; fear of cancer recurrence; self-efficacy; body image; self-report of range of motion; and demographics.
3. After this visit and following surgery, women eligible for Step 2 (i.e., those who received axillary node dissection) will be registered to the intervention portion of this trial.

TREATMENT PLAN

Patients will be randomized to one of two Groups:

ARM A: EDUCATION ONLY*

Education: The CRA will deliver a brief initial post-operative care session describing lymphedema risk and prevention. This educational session is specifically oriented to the needs and concerns of women with breast cancer. It will be delivered by oral instruction and written materials. The lymphedema risk module consists of information about lymphedema etiology, signs, symptoms, treatment, and prevention self-care practices.

Physical assessments and questionnaires: Following the visit with the CRA, the institutional nurse will assess each participant for arm circumference, range of motion, grip strength, and arm strength of both arms. The institutional nurse will also record height and weight. Quality of life and other measures will also be completed at this time.

ARM B: LYMPHEDEMA EDUCATION AND PREVENTION PROGRAM (LEAP)*:

In addition to the education, physical assessment and questionnaires, women enrolled at institutions randomized to the LEAP arm of the study will receive a physical therapy-focused intervention, which includes an assessment conducted by a lymphedema specialist.

Based on the results of the range of motion, grip strength, and arm strength assessments obtained by the institutional nurse, the specialist will provide each woman with an individualized exercise regimen. Each participant will be instructed on the personalized exercise regimen, as well as breathing exercises and sleeve use with instructions to wear it during exercise, heavy/vigorous activity, and air travel. Instructions on arm safety will also be reviewed. The lymphedema specialist will demonstrate the LEAP exercises to the participant, and each participant will be assessed in her performance, given feedback, and re-tested for accuracy and understanding of the regimen.

Women will receive a 15-minute video to take home which reinforces the information and exercises. Calendars, which will be used as reminders, will be supplied for the following three (or six, depending on the timeframe) months in order to record days on which they perform exercises and wear the elastic sleeve, if indicated. Institutions will be provided with the sleeves for the study. Each month will display a reminder to engage in some lymphedema prevention activity.

- **Baseline visit is to take place within 6 weeks following surgery. Follow up evaluations will take place at 6, 12 and 18 months following baseline visit.**
- **Patients will receive a \$10.00 gift certificate after each visit as compensation for parking, gasoline, etc.**