



## Pilot Study of Soy-Based Meal Replacement (Almased®) as a Weight Loss Intervention in Patients With Estrogen Receptor/Progesterone Receptor - Negative Stage I-III Breast Cancer in Complete Remission

Last Modified: 10/16/2007 First Published: 6/16/2006

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### Alternate Title

Soy-Based Meal Replacement in Helping Women With Stage I, Stage II, or Stage III Breast Cancer in Complete Remission Lose Weight

### Basic Trial Information

Phase	Type	Status	Age	Sponsor	Protocol IDs
No phase specified	Behavioral study, Educational/Counseling/Training, Supportive care	Closed	21 and over	NCI	CCCWFU-98904 NCT00343434

### Objectives

- I. Determine the ability to recruit survivors of estrogen receptor/progesterone receptor (ER/PR)-negative stage I-III breast cancer to participate in a 3-month, soy-based, meal-replacement (Almased®) weight loss intervention.
- II. Assess the patient's ability to adhere to this intervention protocol.
- III. Measure changes in anthropometrics (body weight, bioelectrical impedance, waist circumference) and biomarkers (serum levels of glucose, insulin, highly specific C-reactive protein, insulin-like growth factor, insulin-like growth factor binding protein-3, lipids).
- IV. Measure changes in health-related quality of life.

### Entry Criteria

#### Disease Characteristics:

- Previously diagnosed stage I-III breast cancer currently in complete remission
- Completed treatment for breast cancer × 6 months ago
  - Free of disease at last clinic visit
- Body mass index × 27
- Hormone receptor status
  - Estrogen receptor (ER)/progesterone receptor (PR) negative

**Prior/Concurrent Therapy:**

- See Disease Characteristics
- No concurrent medications for weight loss
- No concurrent treatment for ER/PR-negative disease

**Patient Characteristics:**

- Female
- Menopausal status not specified
- No history of soy allergies
- No uncontrolled blood pressure
- No uncontrolled hyperthyroidism or hypothyroidism
- Not pregnant or nursing
- Negative pregnancy test
- Fertile patients must use effective contraception
- No diabetes mellitus (type 1 or 2)
- No medical, psychiatric, or behavioral factors that would preclude study participation
- No definite plans to move out of the area during the study period

**Expected Enrollment**

25

A total of 25 patients will be accrued for this study.

**Outline**

This is a prospective, longitudinal, pilot study.

Patients undergo goal-oriented, cognitive-behavioral therapy comprising group counseling weekly for 3 weeks and individual counseling once a month. Weight loss interventions include behavioral techniques, dietary modification (using a portion-controlled diet and soy-based meal-replacement [Almased®] once or twice daily), physical activity (× 15 minutes per day, 6 days a week), and social support. Weight loss is monitored weekly and patients complete daily logs of dietary intake and physical activity. Therapy continues for 12 weeks.

Health-related quality of life is assessed at baseline and then weekly for 12 weeks.

Patients undergo blood draws at baseline and at 12 weeks for analysis of C-reactive protein, glucose, insulin, insulin-like growth factor (ILGF), and ILGF-binding protein-3.

**Trial Contact Information****Trial Lead Organizations****Wake Forest University Comprehensive Cancer Center**

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**Registry Information**

<b>Official Title</b>	Use of a Soy-Based Meal Replacement Weight Loss Intervention for Survivors of ER/PR Negative Breast Cancer
<b>Trial Start Date</b>	2005-01-27

<b>Registered in ClinicalTrials.gov</b>	<a href="#">NCT00343434</a> <sup>1</sup>
<b>Date Submitted to PDQ</b>	2006-04-18
<b>Information Last Verified</b>	2006-12-03
<b>NCI Grant/Contract Number</b>	CA12197

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**Note:** The purpose of most clinical trials listed in this database is to test new cancer treatments, or new methods of diagnosing, screening, or preventing cancer. Because all potentially harmful side effects are not known before a trial is conducted, dose and schedule modifications may be required for participants if they develop side effects from the treatment or test. The therapy or test described in this clinical trial is intended for use by clinical oncologists in carefully structured settings, and may not prove to be more effective than standard treatment. A responsible investigator associated with this clinical trial should be consulted before using this protocol.

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## Table of Links

<sup>1</sup><http://clinicaltrials.gov/ct/show/NCT00343434>