CALGB-40101:

CYCLOPHOSPHAMIDE AND DOXORUBICIN (CA X 4 CYCLES) VERSUS PACLITAXEL (4 CYCLES) AS ADJUVANT THERAPY FOR BREAST CANCER IN WOMEN WITH 0-3 POSITIVE AXILLARY LYMPH NODES: A PHASE III RANDOMIZED STUDY

ClinicalTrials.gov Identifier: NCT00041119

Study Background

Trial Design: This study was conducted using a phase III factorial design. The factors are chemotherapy agent and treatment length. Cyclophosphamide plus doxorubicin (CA) is the standard agent; the experimental agent is paclitaxel (T). The standard length is shorter (4 cycles) treatment duration; the experimental length is longer (6 cycles) duration. The trial is designed to test (1) the equivalence of the experimental agent T with the standard agent combination CA; and (2) the superiority of longer versus shorter treatment duration. Patients will be randomized with equal probability to one of the four possible treatment arms.

Objectives: Primary:

1. To determine the equivalence of paclitaxel given every two weeks with CA given every two weeks as adjuvant therapy for women with 0-3 positive axillary lymph nodes, for disease-free survival.
2. To determine if longer therapy, 12 weeks, is superior to shorter therapy, 8 weeks, of either CA or paclitaxel for disease-free survival for women with primary breast cancer with 0-3 positive axillary lymph nodes.

Secondary:

- To determine the equivalence of paclitaxel given every two weeks with CA given every two weeks, and the potential superiority of longer vs. shorter therapy, in relation to overall survival, local control (regardless of metastatic status) and time to distant metastases (regardless of local recurrence status).
- To compare toxicities of short and long course CA and paclitaxel as adjuvant therapy for women with 0-3 positive axillary lymph node breast cancer.
- To determine the effect of long and short course CA and paclitaxel on the induction of menopause for pre-menopausal patients.

Stratification Factors:

- Menopausal status (pre vs. post)
- ER/PgR status (either positive or unknown vs both negative)
- HER-2 status (positive, negative or unknown)

Study History:

06/27/2002 Activation Date
07/30/2010 Close Date

Publication Information

Analysis Type:	Primary Endpoint #2: To determine if longer therapy, 12 weeks, is superior to shorter therapy, 8 weeks, of either CA or paclitaxel for disease-free survival for women with primary breast cancer with 0-3 positive axillary lymph nodes.
PubMed ID:	22826271
Citation:	Shulman LN, Cirrincione CT, Berry DA, Becker HP, Perez EA, O'Regan R, Martino S, Atkins JN, Mayer E, Schneider CJ, Kimmick G, Norton L, Muss H, Winer EP, Hudis C. Six cycles of doxorubicin and cyclophosphamide or Paclitaxel are not superior to four cycles as adjuvant chemotherapy for breast cancer in women with zero to three positive axillary nodes: Cancer and Leukemia Group B 40101. J Clin Oncol. 2012 Nov 20;30(33):4071-6. doi: 10.1200/JCO.2011.40.6405
Associated Datasets:	NCT00041119_D1_(FactorA_Patients) NCT00041119_D2_(FactorA_AE)

Dataset Information

Dataset Name: NCT00041119_D2_(FactorA_AE)

Description: The NCT00041119_D2_(FactorA_AE) dataset is one of 2 datasets associated with PubMed ID 22826271. This dataset contains data on reported toxicity reported during treatment.

NCT00041119_D2_(FactorA_AE) Data Dictionary

Variable description	Variable name	Codes	Notes
Mask ID	Mask_id		Deidentified ID corresponds to mask_id in NCT00041119_D1_(FactorA_Patients)
Adeers report submitted	AER_SUBMITTED	1=No 2=Yes	
Meddra code	MEDDRA_CODE		
Meddra dictionary version	MEDDRA_VERSION		
AE grade	GRADE_ID		Grades 3 or 4 adverse events included
Event category	Eventcat		
Event description	eventname		
AE related	Relation_id	1=Unrelated 2=Unlikely 3=Possible 4=Probable 5=Definitely	