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 #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.
PubMed ID:	24934787
Citation:	Shulman LN, Berry DA, Cirrincione CT, Becker HP, Perez EA, O'Regan R, Martino S, Shapiro CL, Schneider CJ, Kimmick G, Burstein HJ, Norton L, Muss H, Hudis CA, Winer EP. Comparison of doxorubicin and cyclophosphamide versus single-agent paclitaxel as adjuvant therapy for breast cancer in women with 0 to 3 positive axillary nodes: CALGB 40101 (Alliance). J Clin Oncol. 2014 Aug 1;32(22):2311-7.
Associated Datasets:	NCT00041119_D3_(FactorB_Patients) NCT00041119_D4_(FactorB_AE)

Dataset Information

Dataset Name: NCT00041119_D3_(FactorB_Patients)

Description: The NCT00041119_D3_(FactorB_Patients) dataset is one of 2 datasets associated with PubMed ID 24934787. This dataset contains de-identified patient-level information. The information includes baseline characteristics, eligibility, and data for the comparison of Doxorubicin and Cyclophosphamide Versus Single-Agent Paclitaxel As Adjuvant Therapy for Breast Cancer.

NCT00041119_D3_(FactorB_Patients) Data Dictionary

Variable description	Variable name	Codes	Notes
De-identified ID	mask_id		
Status ID	SSTAT	7=Alive 8=Dead 9=Lost 65=Withdrawn Consent to follow for survival	
Ethnicity	ETHNIC_ID	1= Hispanic or Latino 2=Non-Hispanic 9=Unknown	
Status ID	Scase	10=On Study 11=Off Study 13=Lost 66=Withdrawn consent to follow for clinical status	
Group	GROUP_ID	1=Alliance for Clinical Trials in Oncology 37=Cancer Trials Support Unit	
Race	RACE_ID	1=White 3=Black or African American 4=Asian 5= Native Hawaiian or Pacific Islander or American Indian or Alaska Native 99=Unknown	
Survival status	survstat	0=Alive 1=Dead	
Eligibility	elig	1=ineligible 2=eligible -1=pending	
Menopause status	stra1	1=pre-menopause 2=post-menopause	
Receptor status	stra2	1=recep+,unk 2=recep-	
Her2-neu status	stra3	1=positive 2=negative 3=unknown	
Treatment assigned	indrx	1=CA-4 2=CA-6 3=T-4 4=T-6	
Tumor laterality	OH002	1=left 2=right 3=bilateral	
Receptor Status ER	OH003	1=Negative 2=Positive	

Variable description	Variable name	Codes	Notes
Receptor Status PgR	OH004	1=Negative 2=Positive	
Histologic grade	OH005	1=Low 2=Intermediate 3=High	
Prior hormonal therapy	OH011	1=no 2=yes	
HT Tamoxifen	OH012	1=no 2=yes	HT = prior hormonal therapy
HT Raloxifen	OH013	1=no 2=yes	HT = prior hormonal therapy
HT Other	OH014	1=no 2=yes	HT = prior hormonal therapy
Prior adjuvant chemo	OH016	1=no 2=yes	
Type biopsy	OH027	1=Core needle 2=Incisional 3=Excisional	
Most extensive primary surgery	OH028	1=Partial mastectomy/lumpectomy/ 2=Mastectomy, NOS	
Sentinel node biopsy	OH032	1=no 2=yes	
Sentinel node biopsy results	OH036	1=negative 2=positive	
Axillary dissection performed	OH037	1=no 2=yes	
Number of positive axillary nodes	num_pos_nodes		
Tumor Size	tsize	1=less than 2cm 2=between 2 and 5cm 3=greater than 5cm	Maximum diameter of the invasive component; if multiple lesions, use longest lesion. Measured in cm
Survival Months	survmos		
Disease Free Survival Months	dfsmos		
Cause of death	cod	0=Alive 1=Due to protocol treatment/Other Cause/Unknown 2=Due to this disease	
Age category	agecat	1=20<=ageatent<30 2=30<=ageatent<40 3=40<=ageatent<50 4=50<=ageatent<60 5=60<=ageatent<70 6=70<=ageatent	Ageatent=age at end of active treatment
Amendment	preamend	1=”preamend” 0=”postamend”	Referring to amendment where 6 cycle arms were closed.
Event	event	1=local only	

Variable description	Variable name	Codes	Notes
		2=dist only 3=loc+dist conc 4=dth, wo rel	
Disease Free Survival Stat	dfsstat	0=no event 1=event	
Agent	agent	0=CA 1=T	
Length of treatment	length	0=4 cycles 1=6 cycles	