CALGB-9741:

A Randomized Phase III Trial of Sequential Chemotherapy Using Doxorubicin, Paclitaxel, and Cyclophosphamide or Concurrent Doxorubicin and Cyclophosphamide Followed by Paclitaxel at 14 or 21 Day Intervals in Women With Node Positive Stage II/IIIA Breast Cancer

ClinicalTrials.gov Identifier: NCT00003088

Study Background

Trial Design: This is a randomized study. Patients are randomized into one of four arms (sequential chemotherapy every 2 weeks vs every 3 weeks vs concurrent chemotherapy followed by paclitaxel every 2 weeks vs every 3 weeks). All tumor should be removed by either a modified radical mastectomy or a segmental mastectomy plus axillary node dissection. Adjuvant chemotherapy is started within 84 days following the last surgical procedure.

- Arm I: Patients receive sequential chemotherapy every 3 weeks. Doxorubicin IV is administered once every 3 weeks for 4 doses. Paclitaxel IV is then administered over 3 hours once every 3 weeks for 4 doses. Cyclophosphamide IV is administered once every 3 weeks for 4 doses following paclitaxel.
- Arm II: Patients receive sequential chemotherapy every 2 weeks. Doxorubicin IV is administered once every 2 weeks for 4 doses. Paclitaxel IV is then administered over 3 hours once every 2 weeks for 4 doses. Cyclophosphamide IV is administered once every 2 weeks for 4 doses following paclitaxel. Filgrastim (G-CSF) is administered by subcutaneous injection on days 3-10 after each dose of doxorubicin, paclitaxel, and cyclophosphamide.
- Arm III: Patients receive combination chemotherapy every 3 weeks. Combination doxorubicin IV and cyclophosphamide IV is administered once every 3 weeks for 4 doses. Paclitaxel IV is administered over 3 hours once every 3 weeks for 4 doses following combination chemotherapy.
- Arm IV: Patients receive combination chemotherapy every 2 weeks. Combination doxorubicin IV and cyclophosphamide IV is administered once every 2 weeks for 4 doses. Paclitaxel IV is administered over 3 hours once every 2 weeks for 4 doses following combination chemotherapy. G-CSF is administered by subcutaneous injection on days 3-10 after each dose of doxorubicin/cyclophophamide and after each dose of paclitaxel.

After completion of all chemotherapy, patients receive tamoxifen orally for 5 years. Patients undergo radiotherapy 4-6 weeks after the completion of chemotherapy. Patients are followed every 6 months for 5 years, then annually until death.

Objectives:

- To compare sequential chemotherapy with doxorubicin, paclitaxel, and cyclophosphamide to combined doxorubicin and cyclophosphamide followed by paclitaxel for disease-free and overall survival.
- To determine whether increasing the dose density of adjuvant chemotherapy (decreasing the interval between chemotherapy courses from 21 to 14 days) will improve disease-free overall survival.
- To compare the toxicity for patients treated with sequential doxorubicin, paclitaxel, and cyclophosphamide followed by paclitaxel at 14 and 21 day intervals.

Stratification Factors: Number of positive lymph nodes (1-3, 4-9, ≥10, sentinel node dissection only)

Study History:

9/15/1997	Activation Date
1/15/1999	Close Date
April 2003	Primary Completion Date
June 2003	Study Completion Date

Publication Information

Analysis Type: Primary Endpoint Analysis

PubMed ID: 12668651

Citation: Citron ML, Berry DA, Cirrincione C, Hudis C, Winer EP, Gradishar WJ, Davidson NE, Martino S, Livingston R, Ingle JN, Perez EA, Carpenter J, Hurd D, Holland JF, Smith BL, Sartor CI, Leung EH, Abrams J, Schilsky RL, Muss HB, Norton L. Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: first report of Intergroup Trial C9741/Cancer and Leukemia Group B Trial 9741. J Clin Oncol. 2003 Apr 15;21(8):1431-9. Epub 2003 Feb 13. Erratum in: J Clin Oncol. 2003 Jun 1;21(11):2226.

Associated Datasets:

NCT00003088_D1_(comp_by_cyc)
NCT00003088_D2_(comp_by_pt)
NCT00003088_D3_(dosered)
NCT00003088_D4_(toxicity)
NCT00003088_D5_(treated)

The following were added 5/18/2018 to include a patient identifier (patid) that ties to NCTN Navigator submissions. Only the inclusion of this patid field has changed from the first 5 datasets.
NCT00003088_D6_(comp_by_cyc)
NCT00003088_D7_(comp_by_pt)
NCT00003088_D8_(dosered)
NCT00003088_D9_(toxicity)
NCT00003088_D10_(treated)

Dataset Information

Dataset Name: NCT00003088_D7_(comp_by_pt)

Description: The NCT00003088_D7_(comp_by_pt) dataset is one of 10 datasets associated with PubMed ID 12668651. This dataset contains data on complications during treatment by patient.

NCT00003088_D7_(comp_by_pt) Data Dictionary

Variable Description	Variable Name	Code	Notes
Patient Identifier	patid		De-identified patient identifier that can be tied to patient information submitted to NCTN Navigator submissions.
De-identified patient identifier	MASK_ID		
Patients with any delay	delay	1 = 'No' 2 = 'Yes'	
Patients hospitalized for febrile neutropenia	hospfn	1 = 'No' 2 = 'Yes'	
Regimen	indrx	1='Seq q3' 2='Seq q2' 3='Con q3' 4='Con q2'	
Patients transfused (RBC)	rbc_tx	1 = 'No' 2 = 'Yes'	