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16-Jan-2026

Trial **2011-004943-32**, NSABP B47

A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

Clinical Trial Results:

This trial was sponsored by Cancer Trials Ireland in Europe however was led and sponsored by NCI in the US. Due to differences in the reporting of specific data fields in the US and EU, certain details required for validation of trial results in EudraCT are not available to us.

We are therefore uploading and posting a summary attachment (download from ClinicalTrials.gov) together with a PDF download from EudraCT of (partial) results of the trial.

Results on CT.gov can be accessed at this link: Study Details | NCT01275677 | Chemotherapy With or Without Trastuzumab After Surgery in Treating Women With Invasive Breast Cancer | ClinicalTrials.gov

They correspond to what is uploaded onto EudraCT.

Cancer Trials Ireland Quality & Training Manager
Charity Regulatory Authority No. 20036676 | Revenue Number CHY12492 | Company Number 268044 a: Cancer Trials Ireland , RCSI House, 121 St. Stephen's Green , Dublin 2 , D02 H903
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Clinical trial results:
A Randomized Phase III Trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six Cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy Plus Trastuzumab in Women with Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer

Summary

EudraCT number	2011-004943-32
Trial protocol	IE
Global end of trial date	02 June 2025

Results information

Result version number	v1 (current)
This version publication date	
First version publication date	

Trial information

Trial identification

Sponsor protocol code	CTRIAL (ICORG) 11-24 NSABP B-47

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01275677
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cancer Trials Ireland
Sponsor organisation address	RCSI House, 121 St. Stephen's Green, Dublin, Ireland, D02 H903
Public contact	Clinical Trials Information, Cancer Trials Ireland, 353 016677211, info@cancertrials.ie
Scientific contact	Clinical Trials Information, Cancer Trials Ireland, 353 016677211, info@cancertrials.ie

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 June 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2017
Global end of trial reached?	Yes
Global end of trial date	02 June 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether the addition of trastuzumab to chemotherapy (TC or AC-WP) improves invasive disease-free survival (IDFS) in women with resected node-positive or high-risk node-negative breast cancer which is reported as HER2-low by all HER2 testing performed.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite guidelines for Good Clinical Practice (GCP), with applicable local regulations SI 190 of 2004 as amend and European Directive 2001/20/EC. The trial was also conducted in accordance with ethical principles founded in the Declaration of Helsinki.
Written informed consent was required for participation.

Background therapy:

N/A

Evidence for comparator:

The primary objective is to compare chemotherapy alone (Six cycles of Doxetaxel Plus Cyclophosphamide or Four cycles of Doxorubicin Plus Cyclophosphamide followed by weekly Paclitaxel) versus chemotherapy regimen plus Trastuzumab.

Actual start date of recruitment	08 February 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	
From 65 to 84 years	
85 years and over	

Subject disposition

Recruitment

Recruitment details:

This study closed to accrual with a total of 3270 patients enrolled worldwide.

Pre-assignment

Screening details:

Patients with Resected Node-Positive or High-Risk Node-Negative Invasive Breast Cancer determined to be HER2-low. Patients must have a life expectancy of at least 10 years (excluding their diagnosis of breast cancer) and fulfil all of the inclusion criteria and none of the exclusion criteria.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm I (Chemotherapy)

Arm description:

GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity.

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity.

Arm type	Active comparator
Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles.

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles.

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity.
GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity.

Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity.

Investigational medicinal product name	Doxorubicin Hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion, Powder for concentrate and solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity.

Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity.

Arm title	Arm II (Chemotherapy, Trastuzamab)

Arm description:

GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity.

GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity.

Arm type	Active comparator
Investigational medicinal product name	Cyclophosphamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA.
GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB.

Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion

Routes of administration	Intravenous use
Dosage and administration details: GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB.	
Investigational medicinal product name	Doxorubicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB.	
Investigational medicinal product name	Doxorubicin Hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB.	
Investigational medicinal product name	Paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB.	
Investigational medicinal product name	Trastuzumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity.	

Number of subjects in period 1[1]	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzamab)
Started	1630	1640
Completed	1602	1598
Not completed	28	42
No follow up	26	37
No Clinical follow up	1	4

Not at risk of recurrence	1	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: This trial was sponsored by Cancer Trials Ireland in Europe however was led and sponsored by NCI in the US. Due to differences in the reporting of specific data fields in the US and EU, certain data is not available.
We are therefore uploading and posting a summary attachment (download from ClinicalTrials.gov).

Baseline characteristics

End points

End points reporting groups

Reporting group title	Arm I (Chemotherapy)

Reporting group description:

GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity.

GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity.

Reporting group title	Arm II (Chemotherapy, Trastuzamab)

Reporting group description:

GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity.

GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity.

Primary: Percentage of Patients Alive and Free from Invasive Disease (IDFS)

End point title	Percentage of Patients Alive and Free from Invasive Disease (IDFS)

End point description:

Please refer to the summary attachment (download from ClinicalTrials.gov) for the reported results for all end points.

End point type	Primary

End point timeframe:

5 years

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Day 1 of first dose through 30 days after Day 1 of last dose.

Adverse event reporting additional description:

B-47 used standard AE reporting based on the descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 4.0.
Please refer to the attached summary report (download from ClinicalTrials.gov) for all reported adverse events.

Assessment type	

Dictionary used

Dictionary name	CTCAE
Dictionary version	4

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: This trial was sponsored by Cancer Trials Ireland in Europe however was led and sponsored by NCI in the US. Due to differences in the reporting of specific data fields in the US and EU, certain details required for validation of trial results in EudraCT are not available to us.
We are therefore uploading and posting a summary attachment (download from ClinicalTrials.gov) which contains details of adverse events reported for this trial.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 December 2011	Protocol Amendment 1_15 September 2011 This version of the protocol was the first version approved in Ireland.
20 January 2012	Protocol Amendment 2_13 December 2011 Updates included: - Administrative changes - Update to Tests, exams, and other requirements during therapy and through Year 1. - Update to AE Reporting Requirements. - Update to TRASTUZUMAB information - Update to NSABP B-47 sample consent form.
14 February 2013	Protocol Amendment 4_2 April 2013 Updates included: - Administrative changes. - Update to Section on Drug Administration. - Update to Study Entry and Withdrawal Procedure. All site staff (NSABP and CTSU sites) will use OPEN to enrol patients.
14 February 2013	Protocol Amendment 3_02 April 2013 Updates include: - Administrative changes - Update to requirements for entry, treatment and follow up. - Update regarding baseline specimen collection. - Update to treatment regimen, If paclitaxel is held, trastuzumab should be continued. - Update to Trastuzumab ordering procedure for U.S and non-U.S sites. - Update to AE Reporting procedure if internet connectivity is disrupted.
17 October 2014	Protocol Amendment 5_16 April 2014 Updates included: - Administrative changes - Update to patient enrolment section of the protocol for instructions on using the Oncology Patient Enrolment Network (OPEN) - Update to Cancer Trials Support Unit (CTSU) Information Resources. - Update to process of submission for completed CRFs (with the exception of patient enrolment forms), clinical reports, and other documents - Update to AE reporting process - Update to Sample Consent Form
02 July 2015	Protocol Amendment 6_28 November 2014 Updates included: - Administrative changes - Update to contraception requirements for women of reproductive potential randomized to Arm 2. - Update to reporting via CTEP-AERS of pregnancy, fetal death, or death neonatal. - Update to Treatment Consent Form.
20 July 2016	Protocol Amendment 7_26 May 2016 Updates included: - Administrative changes - Update to CAEPR Version 2 - Addition of test for AMH levels. - Update to statistical considerations for B-47 Menstrual History study .

23 April 2018	Protocol Amendment 8_8 Feb 2018 - included non-substantial updates.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

ClinicalTrials.gov

National Library of Medicine
National Center for Biotechnology Information

Record 2 of 2

Completed

Chemotherapy With or Without Trastuzumab After Surgery in Treating Women With Invasive Breast Cancer

ClinicalTrials.gov ID NCT01275677

Sponsor National Cancer Institute (NCI)

Information provided by National Cancer Institute (NCI) (Responsible Party)

Last Update Posted 2025-07-14

Results Posted Tab

Results Overview

Conditions

Feedback

HER2/Neu Positive | Progesterone Receptor Positive | Recurrent Breast Carcinoma | Stage IA Breast Cancer AJCC v7 | Stage IB Breast Cancer AJCC v7 | Stage IIA Breast Cancer AJCC v6 and v7 | Stage IIB Breast Cancer AJCC v6 and v7 | Stage IIIA Breast Cancer AJCC v7 | Stage IIIC Breast Cancer AJCC v7

Intervention/Treatment

- Drug: Cyclophosphamide
- Drug: Docetaxel
- Drug: Doxorubicin
- Drug: Doxorubicin Hydrochloride

Show 4 more interventions/treatments

Other Study ID Numbers

- NCI-2011-02572
- NCI-2011-02572 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))

Show 7 more study numbers

Study Design

Allocation: Randomized
Interventional Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Treatment

Results Point of Contact

Name/Title: Director, Department of Regulatory Affairs
Organization: NRG Oncology
Phone: 412-339-5300
Email: langerj@nrgoncology.org

Enrollment (Actual)

3270

Study Type

Interventional

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2011-01-11

First Posted (Estimated)

2011-01-12

Results Reporting Dates

Results First Submitted

2020-05-06

Results First Posted

2020-09-23

Study Record Updates

Last Update Posted

2025-07-14

Last Verified

2025-06

Participant Flow

Recruitment Details

[Not Specified]

Pre-assignment Details

[Not Specified]

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV

Period Title: **Overall Study**

Started	1630	1640

Completed	1602	1598
Not Completed	28	42

Reason Not Completed

Not at risk for recurrence.	1	1
No follow-up	26	37
No clinical follow up.	1	4

Baseline Characteristics

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)	Total
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)	Total of all reporting groups
Overall Number of Baseline Participants	1630	1640	3270
Baseline Analysis Population Description	[Not Specified]		

Expand all / Collapse all

Age, Continuous

Mean (Standard Deviation) | Unit of measure: years

Number Analyzed	1630 participants	1640 participants	3270 participants
	52 (10.4)	52 (10.4)	52 (10.4)

Sex: Female, Male

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	1630 participants	1640 participants	3270 participants
Female	1630 100.0%	1640 100.0%	3270 100.0%
Male	0 0.0%	0 0.0%	0 0.0%

Race (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	1630 participants	1640 participants	3270 participants
American Indian or Alaska Native	8 0.5%	6 0.4%	14 0.4%
Asian	63 3.9%	61 3.7%	124 3.8%
Native Hawaiian or Other Pacific Islander	4 0.2%	7 0.4%	11 0.3%
Black or African American	144 8.8%	175 10.7%	319 9.8%
White	1370 84.0%	1354 82.6%	2724 83.3%

More than one race	9	0.6%	10	0.6%	19	0.6%
Unknown or Not Reported	32	2.0%	27	1.6%	59	1.8%

Race/Ethnicity, Customized

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	1630 participants	1640 participants	3270 participants

Mutually exclusive and exhaustive

Hispanic or Latino	102	6.3%	106	6.5%	208	6.4%
Not Hispanic or Latino	1488	91.3%	1513	92.3%	3001	91.8%
Unknown or Not Reported	40	2.5%	21	1.3%	61	1.9%

Outcome Measures

Expand all / Collapse all

1. Percentage of Patients Alive and Free From Invasive Disease (IDFS)

Type: Primary | Time Frame: 5 years

Description	Percentage of patients free from an invasive disease-free survival event where events include any invasive recurrence, contralateral invasive breast cancer, second non-breast primary cancer (excluding squamous or basal cell carcinoma of the skin), or death from any cause.
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with clinical follow up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1602	1598
	89.2	89.8

Measure Type: Number | Unit of Measure: percentage of patients		

2. Percentage of Patients Alive and Disease-Free (DFS-DCIS)

Type: Secondary | Time Frame: 5 years

Description	Percentage of patients free from a disease-free survival event where events include local recurrence (invasive or DCIS), regional or distant recurrence, contralateral breast cancer (invasive or DCIS), second primary cancer (excluding squamous or basal cell carcinoma of the skin), or death from any cause.
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with clinical follow-up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1602	1598
	89.1	89.6

Measure Type: Number | Unit of Measure: percentage of patients		

3. Percentage of Patients Alive and Free From Breast Cancer (BCFS)

Type: Secondary | Time Frame: 5 years

Description	Percentage of patients free from a breast cancer-free survival event where events include local recurrence (invasive or DCIS), regional or distant recurrence, contralateral breast cancer (invasive or DCIS), or death from any cause.
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with clinical follow up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1602	1598
	91.0	90.7

Measure Type: Number | Unit of Measure: percentage of patients		

4. Percentage of Patients Alive and Recurrence-Free (RFI)

Type: Secondary | Time Frame: 5 years

Description	Percentage of patients free from a recurrence-free interval event where events include invasive local, regional, or distant recurrence, or death from breast cancer (censored for death from other causes).
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with clinical follow-up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1602	1598
	92.3	92.0

Measure Type: Number | Unit of Measure: percentage of patients		

5. Percentage of Patients Alive and Free From Distant Recurrence (DRFI)

Type: Secondary | Time Frame: 5 years

Description	Percentage of patients free from a distant recurrence-free interval event where events include distant recurrence or death from breast cancer (censored for deaths from other causes), regardless of occurrence of any intervening local or regional recurrences, contralateral breast cancers, or non-breast second primary cancer.
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with clinical follow-up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1602	1598
	93.6	92.7

Measure Type: Number | Unit of Measure: percentage of patients		

6. Percentage of Patients Alive (Overall Survival)

Type: Secondary | Time Frame: 5 years

Description	Percentage of patients alive.
Time Frame	5 years
Analysis Population Description	Includes all at-risk patients with follow-up

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1603	1602
	96.3	94.8

Measure Type: Number | Unit of Measure: percentage of patients alive		

7. Toxicity Assessed by Adverse Events

Type: Secondary | Time Frame: While on study therapy. Day 1 of first dose through 30 days after Day 1 of last dose.

Description	Percentage of patients who ever experienced grade 2 or higher toxicites.
Time Frame	While on study therapy. Day 1 of first dose through 30 days after Day 1 of last dose.
Analysis Population Description	Includes all at-risk patients with clinical follow-up.

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	GROUP IA: Patients receive docetaxel IV over 60 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 3 weeks for 6 cycles in the absence of disease progression or unacceptable toxicity. GROUP IB: Patients receive doxorubicin hydrochloride IV over 15 minutes and cyclophosphamide IV over 30 minutes on day 1. Treatment repeats every 2 or 3 weeks for 4 cycles in the absence of disease progression or unacceptable toxicity. Beginning 2-3 weeks after last dose of doxorubicin hydrochloride and cyclophosphamide, patients also receive paclitaxel IV over 60 minutes once weekly for 12 doses in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies	GROUP IIA: Patients receive docetaxel and cyclophosphamide as in Group IA. Patients also receive trastuzumab IV over 30-90 minutes on day 1. Courses repeat every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. GROUP IIB: Patients receive doxorubicin hydrochloride, cyclophosphamide, and paclitaxel as in Group IB. Patients also receive trastuzumab IV over 30-90 minutes weekly for 12 doses and then every 3 weeks for subsequent doses. Treatment repeats every 3 weeks for 1 year in the absence of disease progression or unacceptable toxicity. Cyclophosphamide: Given IV Docetaxel: Given IV Doxorubicin: Given IV Doxorubicin Hydrochloride: Given IV Laboratory Biomarker Analysis: Correlative studies Paclitaxel: Given IV Quality-of-Life Assessment: Ancillary studies Trastuzumab: Given IV
Overall Number of Participants Analyzed	1615	1625
	90.9	94.1

Measure Type: Number | Unit of Measure: percentage of patients		

8. Fcgamma Receptor Polymorphism

Type: Other Pre-specified | Time Frame: From baseline to up to 24 months

Description	The polymorphism of the Fcgamma 158 receptor gene will be dichotomized as V/V (valine) vs. other genotypes and the polymorphism of the Fcgamma 131 receptor gene will be dichotomized as H/H (histidine) vs. other genotypes to evaluate an interaction between treatment group and Fcgamma polymorphism. The Kaplan-Meier method105 will be used to estimate the distribution of the primary endpoints stratified by the dichotomized subgroups, and the log-rank test106 will be used to statistically compare the time-to-event distributions.
Time Frame	From baseline to up to 24 months
Analysis Population Description	[Not Specified]

Outcome Measure Data Not Reported

9. Change in HER2 mRNA Level

Type: Other Pre-specified | Time Frame: From baseline to 24 months

Description	The interaction between treatment effect and HER2 mRNA level will be evaluated in the proportional hazards model, which would include an indicator for treatment group and the HER2 mRNA level as a continuous variable, and the corresponding interaction term. The log-hazard ratio plot for the interaction term with 95% confidence intervals will be used to determine the cut-off of the HER2 mRNA level that would determine a subset of the patients who would benefit from the adjuvant trastuzumab therapy.
Time Frame	From baseline to 24 months

Analysis Population Description	[Not Specified]

Outcome Measure Data Not Reported

Adverse Events

Time Frame
All-Cause Mortality: 5 years; Adverse Events: While on study therapy. Day 1 of first dose through 30 days after Day 1 of last dose.

Adverse Event Reporting Description
B-47 used standard AE reporting based on the descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 4.0. The total at-risk patient groups for adverse events reflect the number of patients who had an AE form or an AdEERS report submitted. The at risk group for all-cause mortality reflects the number who submitted an AE form, an AdEERS report, or a follow-up form, (including follow-up by telephone only).

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)

Expand all / Collapse all

All-Cause Mortality

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	48/1622 (2.96%)	61/1628 (3.75%)

Serious Adverse Events

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	31/1615 (1.92%)	96/1625 (5.91%)
Blood and lymphatic system disorders		
Blood and lymphatic system disorders - Other, specify † 1	0/1615 (0.00%)	1/1625 (0.06%)
Disseminated intravascular coagulation † 1	0/1615 (0.00%)	1/1625 (0.06%)
Cardiac disorders		
Asystole † 1	0/1615 (0.00%)	1/1625 (0.06%)
Heart failure † 1	1/1615 (0.06%)	18/1625 (1.11%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Myocardial infarction †1	2/1615 (0.12%)	2/1625 (0.12%)
Pericardial effusion †1	1/1615 (0.06%)	0/1625 (0.00%)
Supraventricular tachycardia †1	0/1615 (0.00%)	3/1625 (0.18%)
Ventricular tachycardia †1	0/1615 (0.00%)	1/1625 (0.06%)
Acute coronary syndrome †1	1/1615 (0.06%)	0/1625 (0.00%)
Tricuspid valve disease †1	0/1615 (0.00%)	1/1625 (0.06%)
Mitral valve disease †1	0/1615 (0.00%)	1/1625 (0.06%)
Aortic valve disease †1	0/1615 (0.00%)	1/1625 (0.06%)
Left ventricular systolic dysfunction †1	5/1615 (0.31%)	29/1625 (1.78%)
Gastrointestinal disorders		
Colonic perforation †1	1/1615 (0.06%)	0/1625 (0.00%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Diarrhea †1	0/1615 (0.00%)	1/1625 (0.06%)
Typhlitis †1	0/1615 (0.00%)	1/1625 (0.06%)
Upper gastrointestinal hemorrhage †1	0/1615 (0.00%)	1/1625 (0.06%)
General disorders		
Multi-organ failure †1	1/1615 (0.06%)	1/1625 (0.06%)
Hepatobiliary disorders		
Hepatic failure †1	0/1615 (0.00%)	1/1625 (0.06%)
Infections and infestations		
Catheter related infection †1	0/1615 (0.00%)	1/1625 (0.06%)
Hepatitis viral †1	0/1615 (0.00%)	1/1625 (0.06%)
Sepsis †1	2/1615 (0.12%)	7/1625 (0.43%)
Enterocolitis infectious †1	0/1615 (0.00%)	2/1625 (0.12%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Lung infection †1	1/1615 (0.06%)	1/1625 (0.06%)
Small intestine infection †1	1/1615 (0.06%)	0/1625 (0.00%)
Injury, poisoning and procedural complications		
Injury, poisoning and procedural complications - Other, specify †1	0/1615 (0.00%)	1/1625 (0.06%)
Vascular access complication †1	1/1615 (0.06%)	0/1625 (0.00%)
Investigations		
Alanine aminotransferase increased (ALT/SGPT) †1	0/1615 (0.00%)	1/1625 (0.06%)
Aspartate aminotransferase increased (AST/SGOT) †1	0/1615 (0.00%)	1/1625 (0.06%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Lipase increased †1	1/1615 (0.06%)	0/1625 (0.00%)
Ejection fraction decreased †1	1/1615 (0.06%)	10/1625 (0.62%)
Metabolism and nutrition disorders		
Hypercalcemia †1	1/1615 (0.06%)	0/1625 (0.00%)
Hyperglycemia †1	2/1615 (0.12%)	4/1625 (0.25%)
Hypertriglyceridemia †1	0/1615 (0.00%)	1/1625 (0.06%)
Hyperuricemia †1	1/1615 (0.06%)	0/1625 (0.00%)
Hypocalcemia †1	0/1615 (0.00%)	1/1625 (0.06%)
Hypokalemia †1	2/1615 (0.12%)	6/1625 (0.37%)
Hypomagnesemia †1	0/1615 (0.00%)	1/1625 (0.06%)
Hyponatremia †1	0/1615 (0.00%)	1/1625 (0.06%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Myelodysplastic syndrome †1	2/1615 (0.12%)	0/1625 (0.00%)
Leukemia secondary to oncology chemotherapy †1	1/1615 (0.06%)	1/1625 (0.06%)
Nervous system disorders		
Intracranial hemorrhage †1	0/1615 (0.00%)	1/1625 (0.06%)
Stroke †1	0/1615 (0.00%)	1/1625 (0.06%)
Syncope †1	0/1615 (0.00%)	2/1625 (0.12%)
Pregnancy, puerperium and perinatal conditions		
Pregnancy, puerperium and perinatal conditions - Other, specify †1	0/1615 (0.00%)	2/1625 (0.12%)
Psychiatric disorders		
Delirium †1	1/1615 (0.06%)	1/1625 (0.06%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Depression †1	3/1615 (0.19%)	4/1625 (0.25%)
Psychosis †1	0/1615 (0.00%)	1/1625 (0.06%)
Suicide attempt †1	0/1615 (0.00%)	1/1625 (0.06%)
Renal and urinary disorders		
Acute kidney injury †1	0/1615 (0.00%)	1/1625 (0.06%)
Reproductive system and breast disorders		
Vaginal dryness †1	0/1615 (0.00%)	1/1625 (0.06%)
Respiratory, thoracic and mediastinal disorders		
Adult respiratory distress syndrome †1	0/1615 (0.00%)	1/1625 (0.06%)
Dyspnea †1	0/1615 (0.00%)	1/1625 (0.06%)
Hypoxia †1	1/1615 (0.06%)	0/1625 (0.00%)
Pneumonitis †1	7/1615 (0.43%)	5/1625 (0.31%)
Pneumothorax †1	0/1615 (0.00%)	1/1625 (0.06%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Respiratory failure †1	1/1615 (0.06%)	0/1625 (0.00%)
Skin and subcutaneous tissue disorders		
Erythema multiforme †1	0/1615 (0.00%)	1/1625 (0.06%)
Vascular disorders		
Hypertension †1	0/1615 (0.00%)	2/1625 (0.12%)
Hypotension †1	0/1615 (0.00%)	1/1625 (0.06%)
Thromboembolic event †1	1/1615 (0.06%)	0/1625 (0.00%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE v4.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	1362/1615 (84.33%)	1418/1625 (87.26%)
Blood and lymphatic system disorders		
Anemia †1	222/1615 (13.75%)	327/1625 (20.12%)
Gastrointestinal disorders		
Constipation †1	135/1615 (8.36%)	124/1625 (7.63%)
Diarrhea †1	228/1615 (14.12%)	324/1625 (19.94%)
Mucositis oral †1	240/1615 (14.86%)	238/1625 (14.65%)
Nausea †1	408/1615 (25.26%)	377/1625 (23.20%)
Vomiting †1	141/1615 (8.73%)	129/1625 (7.94%)
General disorders		
Fatigue †1	629/1615 (38.95%)	644/1625 (39.63%)
Infections and infestations		
Upper respiratory infection †1	78/1615 (4.83%)	133/1625 (8.18%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Lymphocyte count decreased †1	131/1615 (8.11%)	152/1625 (9.35%)
Neutrophil count decreased †1	145/1615 (8.98%)	166/1625 (10.22%)
White blood cell decreased †1	119/1615 (7.37%)	151/1625 (9.29%)
Ejection fraction decreased †1	3/1615 (0.19%)	164/1625 (10.09%)
Musculoskeletal and connective tissue disorders		
Arthralgia †1	161/1615 (9.97%)	233/1625 (14.34%)
Bone pain †1	228/1615 (14.12%)	221/1625 (13.60%)
Myalgia †1	196/1615 (12.14%)	222/1625 (13.66%)
Nervous system disorders		
Headache †1	164/1615 (10.15%)	187/1625 (11.51%)

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Trastuzumab)
Arm/Group Description	Arm I (chemotherapy)	Arm II (chemotherapy, trastuzumab)
Peripheral sensory neuropathy †1	279/1615 (17.28%)	321/1625 (19.75%)
Psychiatric disorders		
Insomnia †1	108/1615 (6.69%)	128/1625 (7.88%)
Respiratory, thoracic and mediastinal disorders		
Cough †1	80/1615 (4.95%)	136/1625 (8.37%)
Skin and subcutaneous tissue disorders		
Alopecia †1	633/1615 (39.20%)	653/1625 (40.18%)
Vascular disorders		
Hypertension †1	103/1615 (6.38%)	196/1625 (12.06%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE v4.0

Limitations and Caveats

[Not Specified]

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

National Cancer Institute (NCI)

Collaborators

- NRG Oncology

Investigators

- Principal Investigator: Louis Fehrenbacher, NRG Oncology

Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- Fehrenbacher L, Cecchini RS, Geyer CE Jr, Rastogi P, Costantino JP, Atkins JN, Crown JP, Polikoff J, Boileau JF, Provencher L, Stokoe C, Moore TD, Robidoux A, Flynn PJ, Borges VF, Albain KS, Swain SM, Paik S, Mamounas EP, Wolmark N. NSABP B-47/NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy With or Without Trastuzumab in High-Risk Invasive Breast Cancer Negative for HER2 by FISH and With IHC 1+ or 2. J Clin Oncol. 2020 Feb 10;38(5):444-453. doi: 10.1200/JCO.19.01455. Epub 2019 Dec 10. (https://pubmed.ncbi.nlm.nih.gov/31821109)

More Information

Record History

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed