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03-Jun-2026

Trial **2007-003195-19**, ECOG E1505

A phase III Randomised Trial OF Adjuvant Chemotherapy with or without Bevacizumab for patients with Completely Resected Stage IB (≥4 cm) – IIIA Non-Small Cell Lung Cancer (NSCLC).

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 | NCT00324805 | Chemotherapy With or Without Bevacizumab in Treating Patients With Stage IB, Stage II, or Stage IIIA Non-small Cell Lung Cancer That Was Removed By Surgery | 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:
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Clinical trial results:
A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (4 cm) - IIIA Non- Small Cell Lung Cancer (NSCLC)

Summary

EudraCT number	2007-003195-19
Trial protocol	IE
Global end of trial date	31 January 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) 06-36

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00324805
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cancer Trials Ireland
Sponsor organisation address	121 St Stephens Green, Dublin, Ireland, D02 H903
Public contact	Clinical Project Manager, Cancer Trials Ireland (formally ICORG) , Cancer Trials Ireland (formally ICORG), 353 16677211, info@cancertrials.ie
Scientific contact	Clinical Project Manager, Cancer Trials Ireland (formally ICORG) , Cancer Trials Ireland (formally ICORG), 353 16677211, 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	09 April 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 October 2015
Global end of trial reached?	Yes
Global end of trial date	31 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This randomized phase III trial studies chemotherapy and bevacizumab to see how well they work compared to chemotherapy alone in treating patients with stage IB, stage II, or stage IIIA non-small cell lung cancer that was removed by surgery. Drugs used in chemotherapy work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Giving more than one drug (combination chemotherapy) may kill more tumor cells. Monoclonal antibodies, such as bevacizumab, may interfere with the ability of tumor cells to grow and spread. Bevacizumab also may stop the growth of non-small cell lung cancer by blocking the growth of new blood vessels necessary for tumor growth.
The primary objective of the trial is to evaluate overall survival with chemotherapy with or without bevacizumab used in the adjuvant setting in patients with resected stage IB (>= 4 cm) - IIIA non-small cell lung cancer (NSCLC).

Protection of trial subjects:

This clinical study was conducted in accordance with the EU Directive 2001/20/EC and International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP) and the appropriate regulatory requirements.
The trial was also conducted in accordance with ethical principles founded in the Declaration of Helsinki.

Background therapy:

N/A

Evidence for comparator:

The primary objective of the study is to compare overall survival with chemotherapy alone (Arm I) to chemotherapy with bevacizumab (Arm II) in the adjuvant setting in patients with resected stage IB (≥ 4 cm) - IIIA non-small cell lung cancer (NSCLC).

Actual start date of recruitment	19 July 2007
Long term follow-up planned	Yes
Long term follow-up rationale	Scientific research
Long term follow-up duration	10 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Ireland
Country: Number of subjects enrolled	United States
Country: Number of subjects enrolled	Peru
Country: Number of subjects enrolled	Canada
Country: Number of subjects enrolled	South Africa
Worldwide total number of subjects	0
EEA total number of subjects	0

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 months)	0
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:

1501 patients were enrolled to this study between June 1, 2007 and September 20, 2013.

Pre-assignment

Screening details:

In order to be eligible for this trial, patients must have undergone complete resection of their non-small cell lung cancer (NSCLC) [stage IB (≥ 4 cm)] - [IIIA (T2-3N0, T1-3N1, T1-3N2] prior to enrolment 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:

Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity.

REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1
REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1
REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1
REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

Arm type	Active comparator
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 intravenously (IV) on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1
REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1
REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1
REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

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:

REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1

Investigational medicinal product name	Gemcitabine Hydrochloride
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1.

Investigational medicinal product name	Pemetrexed Disodium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

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

Dosage and administration details:

REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 intravenously (IV) on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 .

Arm title	Arm II (Chemotherapy, Bevacizumab)

Arm description:

Patients receive chemotherapy as in Arm I. Patients also receive Bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year.

Arm type	Experimental
Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year.

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

Dosage and administration details:

REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 intravenously (IV) on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1
REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1
REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1
REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

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:

REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1

Investigational medicinal product name	Gemcitabine Hydrochloride
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1.

Investigational medicinal product name	Pemetrexed Disodium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

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

Dosage and administration details:

Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year.

Number of subjects in period 1[1]	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Started	749	752
Completed	599	269
Not completed	150	483
Adverse Event	-	203
Adverse event, non-fatal	62	-
Death	6	9
Other	-	2
Progression	7	35
Did not start therapy	12	17
Alternative therapy	4	8
Other reasons	7	26
Other (Complicating disease)	1	9
Withdrawal by subject	51	174

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: A total of 1,501 patients were enrolled in this study. Due to differences in the reporting of specific data fields between the US and EU registries, a countrylevel breakdown of enrolled patients is not available.

Baseline characteristics

Reporting groups	
Reporting group title	Arm I (Chemotherapy)
Reporting group description:	
Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1	
Reporting group title	Arm II (Chemotherapy, Bevacizumab)
Reporting group description:	
Patients receive chemotherapy as in Arm I. Patients also receive Bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year.	

Reporting group values	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)	Total
Number of subjects	749	752	1501
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	60.7	60.8	
standard deviation	±	±	-
Gender categorical Units: Subjects			
Female	374	381	755
Male	375	371	746
Ethnic Origin Units: Subjects			
Hispanic or Latino	19	29	48
Not Hispanic or Latino	680	688	1368
Unknown or Not Reported	50	35	85
Race Units: Subjects			
American Indian or Alaskan Native	1	5	6
Asian	22	16	38
Native Hawaiian or Other Pacific Islander	3	2	5
Black or African American	74	57	131
White	642	660	1302
More than one race	0	0	0
Unknown or Not Reported	7	12	19

End points

End points reporting groups

Reporting group title	Arm I (Chemotherapy)

Reporting group description:

Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity.

REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1
REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1
REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1
REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1

Reporting group title	Arm II (Chemotherapy, Bevacizumab)

Reporting group description:

Patients receive chemotherapy as in Arm I. Patients also receive Bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year.

Primary: Overall Survival

End point title	Overall Survival[1]

End point description:

Please refer to the summary attachment (download of results posted on ClinicalTrials.gov) for all results related to Primary and Secondary Endpoints.

End point type	Primary

End point timeframe:

From registration to death, up to 10 years

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: 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 were not available.
Please refer to summary attachment (download from ClinicalTrials.gov) which contains End Point results and associated statistical analysis.

End point values	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	749	752		
Units: Months				
number (confidence interval 95%)	(to)	(to)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Assessed every 3 weeks while on treatment and for 30 days after the end of treatment	
Adverse event reporting additional description:	
One patient who did not start treatment submitted an adverse event report	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.0

Frequency threshold for reporting non-serious adverse events: 5 %

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: 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 were not available.
Please refer to 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
20 December 2007	Addendum #4 (Protocol Version dated 26-Jun-2007): Updates included to changes to patient selection criteria. Protocol Addendum #1-3 were incorporated to Protocol version 01-Jun-2007 prior to activation.
27 June 2008	Addendum #5 (Protocol Version date 12-Feb-2008): Updates included changes to tests required, updated eligibility criteria and administrative changes
13 August 2009	Addendum #7 (Protocol Version dated 18-Feb-2009) Updates included scientific and therapeutic changes, updates to eligibility criteria and administrative changes.
13 August 2009	Addendum #6 (Protocol Version dated 7-Jan-2009) Updates included scientific and therapeutic changes, updates to eligibility criteria and administrative changes.
23 September 2010	Addendum #8 (Protocol version dated 10-Jun-2010) Updates included therapeutic changes, administrative changes, changes to eligibility criteria. and Addendum #9 (Protocol version dated 30-Jul-2010) Updates included administrative changes, updates to the eligibility criteria, and changes bevacizumab adverse reactions.
21 October 2011	Addendum# 10 (Protocol Version dated 26-Aug-2011) This amendment updated the CTEP CTCAE Version 3.0 to CTCAE version 4.0 conversion.
20 March 2012	Addendum #11 (Protocol Version dated 8-Dec-2011) Updates included changes made in response to the Action Letter for Bevacuzimab (rhuMAb VEGF, NSC 704865) issued by the NCI dated 15 Dec 2011. The risk of ovarian failure was added to the Patient Information Leaflet and Consent Form. This risk is only applicable to female, premenopausal patients and does not pose a risk to the majority of patients that will be eligible for this trial. Accrual of premenopausal women was suspended until approval by Irish Medicines Board and Central Ethics Committee was in place.
11 October 2012	Addendum #12 (Protocol Version dated29-Jun-2012) Updates included clarification and emphasis of existing eligibility criteria, new instruction referring sites to the Bevacuzimab CAEPR for side effects of Bevacuzimab and additional administrative updates.
05 December 2014	Addendum #13 (Protocol Version dated 18-Jun-2014) Changes included reformatting of entire protocol including the removal of the Informed Consent document from the protocol and other administrative changes. and Addendum #14 (Protocol Version dated 20-Jun-2014) Changes included updated CAEPR for Bevacizumab, updates to risks of the study and other administrative changes.
17 April 2015	Addendum #15 changes (Protocol Version dated 19-Dec-2014) Updates included the replacement of 'Bevacizumab' with the word 'medications' to clarify risks are related to all study agents and other administrative changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Completed

Chemotherapy With or Without Bevacizumab in Treating Patients With Stage IB, Stage II, or Stage IIIA Non-small Cell Lung Cancer That Was Removed By Surgery

ClinicalTrials.gov ID NCT00324805

Sponsor National Cancer Institute (NCI)

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

Last Update Posted 2025-03-03

Results Posted Tab

Results Overview

Conditions

Stage IB Lung Non-Small Cell Carcinoma AJCC v7

Stage IIA Lung Non-Small Cell Carcinoma AJCC v7

Stage IIB Lung Non-Small Cell Carcinoma AJCC v7

Stage IIIA Lung Non-Small Cell Cancer AJCC v7

Intervention/Treatment

- Biological: Bevacizumab
- Drug: Cisplatin
- Drug: Docetaxel
- Drug: Gemcitabine Hydrochloride

Show 4 more interventions/treatments

Other Study ID Numbers

- NCI-2009-00509
- NCI-2009-00509 (Registry Identifier) (REGISTRY: CTRP (Clinical Trial Reporting Program))

Show 8 more study numbers

Study Design

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

Results Point of Contact

Name/Title: Study Statistician
Organization: ECOG-ACRIN Statistical Center
Phone: 617-632-3012

Enrollment (Actual)

1501

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

2006-05-10

First Submitted that Met QC Criteria

2006-05-10

First Posted (Estimated)

2006-05-11

Results Reporting Dates

Results First Submitted

2018-01-12

Results First Submitted that Met QC Criteria

2018-02-12

Results First Posted

2018-02-14

Study Record Updates

Last Update Submitted that Met QC Criteria

2025-02-28

Last Update Posted

2025-03-03

Last Verified

2025-02

Participant Flow

Recruitment Details
Patients were recruited between June 1, 2007 and September 20, 2013 from ECOG-ACRIN, SWOG, RTOG, CALGB, NCCTG, NCIC-CTG, NSABP, ACOSOG, and CTSU sites.

Pre-assignment Details
[Not Specified]

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 intravenously (IV) on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV

Period Title: **Overall Study**

Started	749	752
Started Assigned Therapy	737	735
Completed	599	269

Not Completed	150	483

Reason Not Completed

Adverse Event	62	203
Progression	7	35
Withdrawal by Subject	51	174
Death	6	9
Alternative therapy	4	8
Other complicating disease	1	9
Other reasons	7	26
Other	0	2
Did not start therapy	12	17

Baseline Characteristics

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)	Total
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Total of all reporting groups
Overall Number of Baseline Participants	749	752	1501
Baseline Analysis Population Description	All randomized patients		

Age, Continuous

Mean (Standard Deviation) | Unit of measure: years

Number Analyzed	749 participants	752 participants	1501 participants
	60.7 (9.0)	60.8 (8.7)	60.8 (8.8)

Sex: Female, Male

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

Number Analyzed	749 participants	752 participants	1501 participants
Female	374 49.9%	381 50.7%	755 50.3%
Male	375 50.1%	371 49.3%	746 49.7%

Ethnicity (NIH/OMB)

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

Number Analyzed	749 participants	752 participants	1501 participants
Hispanic or Latino	19 2.5%	29 3.9%	48 3.2%
Not Hispanic or Latino	680 90.8%	688 91.5%	1368 91.1%
Unknown or Not Reported	50 6.7%	35 4.7%	85 5.7%

Race (NIH/OMB)

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

Number Analyzed	749 participants		752 participants		1501 participants	
American Indian or Alaska Native	1	0.1%	5	0.7%	6	0.4%
Asian	22	2.9%	16	2.1%	38	2.5%
Native Hawaiian or Other Pacific Islander	3	0.4%	2	0.3%	5	0.3%
Black or African American	74	9.9%	57	7.6%	131	8.7%
White	642	85.7%	660	87.8%	1302	86.7%
More than one race	0	0.0%	0	0.0%	0	0.0%
Unknown or Not Reported	7	0.9%	12	1.6%	19	1.3%

Chemotherapy

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

Number Analyzed	749 participants		752 participants		1501 participants	
Cisplatin/Vinorelbine	187	25.0%	190	25.3%	377	25.1%
Cisplatin/Docetaxel	172	23.0%	171	22.7%	343	22.9%
Cisplatin/Gemcitabine	142	19.0%	141	18.8%	283	18.9%

Cisplatin/Pemetrexed	248 33.1%	249 33.1%	497 33.1%
Unknown/Missing	0 0.0%	1 0.1%	1 0.1%

Histology

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

Number Analyzed	749 participants	752 participants	1501 participants
Squamous	216 28.8%	206 27.4%	422 28.1%
Adenocarcinoma	424 56.6%	450 59.8%	874 58.2%
Large cell	22 2.9%	16 2.1%	38 2.5%
Bronchioloalveolar carcinoma (BAC)	8 1.1%	5 0.7%	13 0.9%
Not otherwise specified (NOS)	24 3.2%	16 2.1%	40 2.7%
Combined/mixed	45 6.0%	48 6.4%	93 6.2%
Other	10 1.3%	10 1.3%	20 1.3%
Unknown/missing	0 0.0%	1 0.1%	1 0.1%

Performance Status

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

Number Analyzed	749 participants	752 participants	1501 participants

Fully active	439 58.6%	440 58.5%	879 58.6%
Ambulatory	310 41.4%	310 41.2%	620 41.3%
Unknown/missing	0 0.0%	2 0.3%	2 0.1%

Urine protein:creatinine (UPC) ratio

Mean (Standard Deviation) | Unit of measure: ratio

Number Analyzed	749 participants	752 participants	1501 participants
	0.31 (3.10)	0.18 (0.92)	0.25 (2.28)

Urine protein

Mean (Standard Deviation) | Unit of measure: mg/dL

Number Analyzed	749 participants	752 participants	1501 participants
	95.26 (32.28)	100.25 (32.28)	97.79 (41.86)

Outcome Measures

Expand all / Collapse all

1. Overall Survival

Type: Primary | Time Frame: From registration to death, up to 10 years

Description	Overall survival (OS) was defined as the time from randomization to death from any cause, and patients who were thought to be alive at the time of final analysis were censored at the last date of contact. The study failed to meet its primary endpoint.
Time Frame	From registration to death, up to 10 years
Analysis Population Description	All enrolled patients

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV
Overall Number of Participants Analyzed	749	752
Median (95% Confidence Interval) | Unit of Measure: months	NA [1] (NA to NA)	85.8 [2] (74.9 to NA)

[1] The median overall survival and corresponding 95% confidence interval were not calculable because an insufficient number of participants reached the

event at the final time point for assessment, i.e. a median has not been reached

[2] The upper limit of the 95% confidence interval was not calculable because an insufficient number of participants reached the event at the final time point for assessment.

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm I (Chemotherapy), Arm II (Chemotherapy, Bevacizumab)
Comments	[Not Specified]
Type of Statistical Test	Superiority
Comments	[Not Specified]

Statistical Test of Hypothesis

P-Value	0.90
Comments	[Not Specified]
Method	Regression, Cox
Comments	[Not Specified]

Method of Estimation

Estimation Parameter	Hazard Ratio (HR)
Estimated Value	0.99
Confidence Interval	(2-Sided) 95% 0.82 to 1.19
Estimation Comments	Arm II versus Arm I

2. Disease-free Survival

Type: Secondary | Time Frame: From registration to death, up to 10 years

Description	Disease-free survival (DFS) was defined as the time from randomization to an event. Events include disease recurrence, new primary of lung cancer, second primaries or death, whichever occurred first; however, it should be noted that patients with new primaries at other non-lung sites should have continued followup for recurrence of the original cancer. Patients that have not had an event reported at analysis were censored at their last date of disease assessment.
Time Frame	From registration to death, up to 10 years
Analysis Population Description	All enrolled patients

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV
Overall Number of Participants Analyzed	749	752
Median (95% Confidence Interval) | Unit of Measure: months	42.9 (36.7 to 57.0)	40.6 (35.5 to 49.5)

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Arm I (Chemotherapy), Arm II (Chemotherapy, Bevacizumab)
Comments	[Not Specified]
Type of Statistical Test	Superiority
Comments	[Not Specified]

Statistical Test of Hypothesis

P-Value	0.95
Comments	[Not Specified]
Method	Regression, Cox
Comments	[Not Specified]

Method of Estimation

Estimation Parameter	Hazard Ratio (HR)
Estimated Value	0.99
Confidence Interval	(2-Sided) 95% 0.86 to 1.15

Estimation Comments	Arm II vs. Arm I

3. Toxicity Rates as Assessed by the National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0

Type: Other Pre-specified | Time Frame: Up to 1 year post-treatment

Description	If the difference in the rate of a particular category of toxicities between the 2 arms (N=750 per arm) is at least 5% (4% vs. 9%), 96% power can be attained assuming a significance level of 5% (two-sided Chi Square test) and that the lower toxicity rate for one arm is 4%. A difference in the rates of grade 3-5 arterial thromboembolic events and bleeding events will be monitored and assessed between the treatment arms.
Time Frame	Up to 1 year post-treatment
Analysis Population Description	[Not Specified]

Outcome Measure Data Not Reported

4. Perform Analyses of Tissue and Blood to Establish Factors That Predict for Clinical Outcome in Patients Receiving Chemotherapy, With or Without Bevacizumab, for Resected Early Stage NSCLC.

Type: Other Pre-specified | Time Frame: From registration to death, up to 10 years

Description	[Not Specified]
Time Frame	From registration to death, up to 10 years
Analysis Population Description	Data for these studies were not collected

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total analyzed.

5. To Determine Whether Smoking Status is Linked to Outcome for Patients With Resected Stage IB - IIIA NSCLC Treated With Chemotherapy With or Without Bevacizumab in the Adjuvant Setting.

Type: Other Pre-specified | Time Frame: From registration to death, up to 10 years

Description	[Not Specified]	
Time Frame	From registration to death, up to 10 years	
Analysis Population Description	Data were not collected	
Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV
Overall Number of Participants Analyzed	0	0

No data displayed because Outcome Measure has zero total analyzed.

Adverse Events

Time Frame
Assessed every 3 weeks while on treatment and for 30 days after the end of treatment

Adverse Event Reporting Description
One patient who did not start treatment submitted an adverse event report

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
Arm/Group Description	Patients receive one of the following. For all, treatment repeats every 21 days for up to 4 courses in the absence of disease progression or unacceptable toxicity. REGIMEN 1: Vinorelbine ditartrate 30 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV over 60 minutes on day 1 REGIMEN 2: Docetaxel 75 mg/m2 IV and cisplastin 75 mg/m2 IV on day 1 REGIMEN 3: Gemcitabine hydrochloride 1200 mg/m2 IV on days 1 and 8, cisplatin 75 mg/m2 IV on day 1 REGIMEN 4 (non-squamous histology only): Pemetrexed disodium 500mg/m2 IV and cisplatin 75 mg/m2 IV on day 1 Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV	Patients receive chemotherapy as in Arm I. Patients also receive bevacizumab IV over 30-90 minutes on day 1. Treatment with bevacizumab repeats every 21 days for up to 1 year. Bevacizumab: Given IV Cisplatin: Given IV Docetaxel: Given IV Gemcitabine Hydrochloride: Given IV Pemetrexed Disodium: Given IV Vinorelbine: Given IV

Expand

All-Cause Mortality

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	–/–	–/–

Serious Adverse Events

Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	424/738 (57.45%)	563/735 (76.60%)
Blood and lymphatic system disorders		
Anemia †1	52/738 (7.05%)	40/735 (5.44%)
Febrile neutropenia †1	31/738 (4.20%)	43/735 (5.85%)
Cardiac disorders		
Acute coronary syndrome †1	0/738 (0.00%)	1/735 (0.14%)
Atrial fibrillation †1	2/738 (0.27%)	2/735 (0.27%)
Atrial flutter †1	0/738 (0.00%)	1/735 (0.14%)
Cardiac arrest †1	0/738 (0.00%)	1/735 (0.14%)
Chest pain - cardiac †1	0/738 (0.00%)	1/735 (0.14%)
Heart failure †1	0/738 (0.00%)	3/735 (0.41%)
Left ventricular systolic dysfunction †1	1/738 (0.14%)	1/735 (0.14%)

Myocardial infarction †1	1/738 (0.14%)	7/735 (0.95%)
Sinus tachycardia †1	0/738 (0.00%)	2/735 (0.27%)
Cardiac disorders - Other, specify †1	1/738 (0.14%)	0/735 (0.00%)
Ear and labyrinth disorders		
Hearing impaired †1	6/738 (0.81%)	2/735 (0.27%)
Tinnitus †1	4/738 (0.54%)	4/735 (0.54%)
Eye disorders		
Blurred vision †1	1/738 (0.14%)	1/735 (0.14%)
Photophobia †1	0/738 (0.00%)	1/735 (0.14%)
Retinal detachment †1	0/738 (0.00%)	1/735 (0.14%)
Gastrointestinal disorders		
Abdominal distension †1	0/738 (0.00%)	2/735 (0.27%)
Abdominal pain †1	5/738 (0.68%)	22/735 (2.99%)
Cheilitis †1	1/738 (0.14%)	0/735 (0.00%)
Colitis †1	5/738 (0.68%)	2/735 (0.27%)

Colonic hemorrhage †1	0/738 (0.00%)	2/735 (0.27%)
Colonic obstruction †1	0/738 (0.00%)	1/735 (0.14%)
Colonic perforation †1	1/738 (0.14%)	1/735 (0.14%)
Constipation †1	8/738 (1.08%)	5/735 (0.68%)
Diarrhea †1	15/738 (2.03%)	31/735 (4.22%)
Duodenal perforation †1	0/738 (0.00%)	1/735 (0.14%)
Dyspepsia †1	1/738 (0.14%)	1/735 (0.14%)
Dysphagia †1	1/738 (0.14%)	2/735 (0.27%)
Enterocolitis †1	1/738 (0.14%)	1/735 (0.14%)
Esophageal pain †1	1/738 (0.14%)	0/735 (0.00%)
Gastric hemorrhage †1	0/738 (0.00%)	1/735 (0.14%)
Gastritis †1	1/738 (0.14%)	2/735 (0.27%)
Gastroesophageal reflux disease †1	1/738 (0.14%)	0/735 (0.00%)
Gastrointestinal pain †1	1/738 (0.14%)	0/735 (0.00%)

Ileus †1	3/738 (0.41%)	3/735 (0.41%)
Mucositis oral †1	4/738 (0.54%)	12/735 (1.63%)
Nausea †1	63/738 (8.54%)	74/735 (10.07%)
Pancreatitis †1	1/738 (0.14%)	0/735 (0.00%)
Rectal hemorrhage †1	0/738 (0.00%)	2/735 (0.27%)
Small intestinal obstruction †1	1/738 (0.14%)	1/735 (0.14%)
Stomach pain †1	1/738 (0.14%)	1/735 (0.14%)
Toothache †1	0/738 (0.00%)	1/735 (0.14%)
Vomiting †1	38/738 (5.15%)	47/735 (6.39%)
Gastrointestinal disorders - Other †1	1/738 (0.14%)	2/735 (0.27%)
General disorders		
Fatigue †1	66/738 (8.94%)	92/735 (12.52%)
Fever †1	0/738 (0.00%)	2/735 (0.27%)
Infusion site extravasation †1	0/738 (0.00%)	1/735 (0.14%)

Multi-organ failure †1	0/738 (0.00%)	1/735 (0.14%)
Non-cardiac chest pain †1	3/738 (0.41%)	6/735 (0.82%)
Pain †1	2/738 (0.27%)	1/735 (0.14%)
Sudden death NOS †1	0/738 (0.00%)	1/735 (0.14%)
Hepatobiliary disorders		
Cholecystitis †1	0/738 (0.00%)	1/735 (0.14%)
Immune system disorders		
Allergic reaction †1	0/738 (0.00%)	1/735 (0.14%)
Anaphylaxis †1	7/738 (0.95%)	6/735 (0.82%)
Autoimmune disorder †1	1/738 (0.14%)	0/735 (0.00%)
Cytokine release syndrome †1	0/738 (0.00%)	1/735 (0.14%)
Serum sickness †1	0/738 (0.00%)	1/735 (0.14%)
Infections and infestations		
Anorectal infection †1	1/738 (0.14%)	0/735 (0.00%)
Bladder infection †1	0/738 (0.00%)	1/735 (0.14%)

Bronchial infection †1	3/738 (0.41%)	1/735 (0.14%)
Catheter related infection †1	0/738 (0.00%)	3/735 (0.41%)
Device related infection †1	1/738 (0.14%)	0/735 (0.00%)
Enterocolitis infectious †1	2/738 (0.27%)	2/735 (0.27%)
Esophageal infection †1	0/738 (0.00%)	1/735 (0.14%)
Gum infection †1	2/738 (0.27%)	0/735 (0.00%)
Lung infection †1	8/738 (1.08%)	11/735 (1.50%)
Pleural infection †1	0/738 (0.00%)	2/735 (0.27%)
Sepsis †1	4/738 (0.54%)	5/735 (0.68%)
Skin infection †1	2/738 (0.27%)	1/735 (0.14%)
Tooth infection †1	0/738 (0.00%)	1/735 (0.14%)
Upper respiratory infection †1	1/738 (0.14%)	4/735 (0.54%)
Urinary tract infection †1	4/738 (0.54%)	5/735 (0.68%)

Infections and infestations - Other † 1	10/738 (1.36%)	18/735 (2.45%)
Injury, poisoning and procedural complications		
Vascular access complication † 1	2/738 (0.27%)	3/735 (0.41%)
Wound dehiscence † 1	0/738 (0.00%)	4/735 (0.54%)
Investigations		
Alanine aminotransferase increased † 1	2/738 (0.27%)	0/735 (0.00%)
Alkaline phosphatase increased † 1	1/738 (0.14%)	0/735 (0.00%)
Aspartate aminotransferase increased † 1	2/738 (0.27%)	0/735 (0.00%)
Cardiac troponin I increased † 1	1/738 (0.14%)	0/735 (0.00%)
Creatinine increased † 1	6/738 (0.81%)	9/735 (1.22%)
INR increased † 1	0/738 (0.00%)	1/735 (0.14%)
Lipase increased † 1	1/738 (0.14%)	1/735 (0.14%)

Lymphocyte count decreased †1	7/738 (0.95%)	11/735 (1.50%)
Neutrophil count decreased †1	237/738 (32.11%)	273/735 (37.14%)
Platelet count decreased †1	30/738 (4.07%)	44/735 (5.99%)
Weight loss †1	1/738 (0.14%)	1/735 (0.14%)
White blood cell decreased †1	41/738 (5.56%)	42/735 (5.71%)
Investigations - Other, specify †1	1/738 (0.14%)	1/735 (0.14%)
Metabolism and nutrition disorders		
Acidosis †1	0/738 (0.00%)	2/735 (0.27%)
Anorexia †1	9/738 (1.22%)	19/735 (2.59%)
Dehydration †1	40/738 (5.42%)	45/735 (6.12%)
Hypercalcemia †1	1/738 (0.14%)	0/735 (0.00%)
Hyperglycemia †1	11/738 (1.49%)	9/735 (1.22%)
Hyperkalemia †1	4/738 (0.54%)	1/735 (0.14%)

Hypoalbuminemia †1	1/738 (0.14%)	3/735 (0.41%)
Hypocalcemia †1	3/738 (0.41%)	6/735 (0.82%)
Hypoglycemia †1	0/738 (0.00%)	1/735 (0.14%)
Hypokalemia †1	20/738 (2.71%)	13/735 (1.77%)
Hypomagnesemia †1	5/738 (0.68%)	4/735 (0.54%)
Hyponatremia †1	44/738 (5.96%)	66/735 (8.98%)
Hypophosphatemia †1	0/738 (0.00%)	4/735 (0.54%)

Musculoskeletal and connective tissue disorders

Arthralgia †1	3/738 (0.41%)	5/735 (0.68%)
Back pain †1	0/738 (0.00%)	1/735 (0.14%)
Bone pain †1	0/738 (0.00%)	1/735 (0.14%)
Chest wall pain †1	0/738 (0.00%)	1/735 (0.14%)
Generalized muscle weakness †1	6/738 (0.81%)	7/735 (0.95%)
Muscle weakness lower limb †1	0/738 (0.00%)	1/735 (0.14%)
Myalgia †1	4/738 (0.54%)	2/735 (0.27%)

Neck pain †1	0/738 (0.00%)	1/735 (0.14%)
Pain in extremity †1	1/738 (0.14%)	1/735 (0.14%)
Nervous system disorders		
Ataxia †1	1/738 (0.14%)	3/735 (0.41%)
Cognitive disturbance †1	1/738 (0.14%)	1/735 (0.14%)
Dizziness †1	4/738 (0.54%)	12/735 (1.63%)
Dysphasia †1	1/738 (0.14%)	1/735 (0.14%)
Headache †1	5/738 (0.68%)	18/735 (2.45%)
Intracranial hemorrhage †1	1/738 (0.14%)	1/735 (0.14%)
Ischemia cerebrovascular †1	0/738 (0.00%)	1/735 (0.14%)
Memory impairment †1	0/738 (0.00%)	1/735 (0.14%)
Neuralgia †1	0/738 (0.00%)	1/735 (0.14%)
Peripheral motor neuropathy †1	2/738 (0.27%)	1/735 (0.14%)

Peripheral sensory neuropathy † 1	5/738 (0.68%)	5/735 (0.68%)
Reversible posterior leukoencephalopathy † 1	0/738 (0.00%)	3/735 (0.41%)
Seizure † 1	1/738 (0.14%)	3/735 (0.41%)
Stroke † 1	1/738 (0.14%)	0/735 (0.00%)
Syncope † 1	8/738 (1.08%)	10/735 (1.36%)
Nervous system disorders - Other † 1	0/738 (0.00%)	5/735 (0.68%)
Psychiatric disorders		
Anxiety † 1	1/738 (0.14%)	0/735 (0.00%)
Confusion † 1	1/738 (0.14%)	4/735 (0.54%)
Depression † 1	3/738 (0.41%)	0/735 (0.00%)
Insomnia † 1	0/738 (0.00%)	2/735 (0.27%)
Renal and urinary disorders		
Acute kidney injury † 1	6/738 (0.81%)	6/735 (0.82%)
Chronic kidney disease † 1	1/738 (0.14%)	3/735 (0.41%)

Hematuria †1	0/738 (0.00%)	1/735 (0.14%)
Proteinuria †1	2/738 (0.27%)	17/735 (2.31%)
Urinary retention †1	1/738 (0.14%)	0/735 (0.00%)
Reproductive system and breast disorders		
Testicular pain †1	1/738 (0.14%)	0/735 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Aspiration †1	2/738 (0.27%)	1/735 (0.14%)
Bronchopleural fistula †1	0/738 (0.00%)	2/735 (0.27%)
Bronchopulmonary hemorrhage †1	0/738 (0.00%)	3/735 (0.41%)
Cough †1	2/738 (0.27%)	6/735 (0.82%)
Dyspnea †1	8/738 (1.08%)	17/735 (2.31%)
Epistaxis †1	2/738 (0.27%)	4/735 (0.54%)
Hoarseness †1	0/738 (0.00%)	1/735 (0.14%)
Hypoxia †1	0/738 (0.00%)	5/735 (0.68%)
Laryngeal edema †1	0/738 (0.00%)	1/735 (0.14%)

Pleural effusion †1	1/738 (0.14%)	2/735 (0.27%)
Pneumonitis †1	3/738 (0.41%)	1/735 (0.14%)
Pulmonary hypertension †1	1/738 (0.14%)	1/735 (0.14%)
Respiratory failure †1	0/738 (0.00%)	1/735 (0.14%)
Respiratory thoracic mediastinal - Other †1	1/738 (0.14%)	1/735 (0.14%)
Skin and subcutaneous tissue disorders		
Rash maculo-papular †1	1/738 (0.14%)	3/735 (0.41%)
Stevens-Johnson syndrome †1	0/738 (0.00%)	1/735 (0.14%)
Vascular disorders		
Hematoma †1	0/738 (0.00%)	1/735 (0.14%)
Hypertension †1	19/738 (2.57%)	200/735 (27.21%)
Hypotension †1	7/738 (0.95%)	11/735 (1.50%)
Peripheral ischemia †1	0/738 (0.00%)	1/735 (0.14%)
Thromboembolic event †1	12/738 (1.63%)	33/735 (4.49%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE 4.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%	
Arm/Group Title	Arm I (Chemotherapy)	Arm II (Chemotherapy, Bevacizumab)
	Affected / at Risk (%)	Affected / at Risk (%)
Total	474/738 (64.23%)	509/735 (69.25%)
Blood and lymphatic system disorders		
Anemia †1	256/738 (34.69%)	183/735 (24.90%)
General disorders		
Fatigue †1	62/738 (8.40%)	68/735 (9.25%)
Investigations		
Creatinine increased †1	169/738 (22.90%)	247/735 (33.61%)
Neutrophil count decreased †1	220/738 (29.81%)	236/735 (32.11%)

Platelet count decreased †1	48/738 (6.50%)	49/735 (6.67%)
Nervous system disorders		
Peripheral sensory neuropathy †1	53/738 (7.18%)	58/735 (7.89%)
Renal and urinary disorders		
Proteinuria †1	3/738 (0.41%)	48/735 (6.53%)
Vascular disorders		
Hypertension †1	2/738 (0.27%)	50/735 (6.80%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE 4.0

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

- Cancer and Leukemia Group B
- NCIC Clinical Trials Group
- North Central Cancer Treatment Group
- SWOG Cancer Research Network

Investigators

- Principal Investigator: Heather A Wakelee, ECOG-ACRIN Cancer Research Group

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.

- Wang Y, Sun Z, Sridhar A, Ramalingam SS, Wakelee HA, Gerber DE. Participation in lung cancer biospecimen studies: an analysis of the ECOG-ACRIN phase 3 E1505 and E5508 clinical trials. Lung Cancer. 2026 Apr;214:109304. doi: 10.1016/j.lungcan.2026.109304. Epub 2026 Feb 7. (https://pubmed.ncbi.nlm.nih.gov/41666849)

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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