Trial record **1 of 1** for: h3e-mc-jmho
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Study of Pemetrexed and Carboplatin Compared With Etoposide Carboplatin to Treat Extensive-Stage Small Cell Lung Cancer

This study has been completed.

Sponsor:
Eli Lilly and Company

Information provided by:
Eli Lilly and Company

ClinicalTrials.gov Identifier:
NCT00363415

First received: August 10, 2006
Last updated: October 20, 2009
Last verified: October 2009
History of Changes

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Results First Received: June 5, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Small Cell Lung Cancer
Interventions:	

	Drug: pemetrexed Drug: etoposide Drug: carboplatin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants who received at least one dose of study drug were, per protocol, the patient population used for the summary of safety data (eg, Serious Adverse Events).

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Participant Flow: Overall Study

	Pemetrexed + Carboplatin	Etoposide + Carboplatin
STARTED	**453**	**455**
Received at Least One Dose of Study Drug	**433**	**447**

COMPLETED	**92**	**206**
NOT COMPLETED	**361**	**249**
Progressive Disease	**196**	**107**
Sponsor Decision	**67**	**31**
Death	**32**	**29**
Adverse Event	**24**	**15**
Physician Decision	**18**	**35**
Entry Criteria Not Met	**11**	**10**
Withdrawal by Subject	**9**	**15**
Lost to Follow-up	**3**	**3**
Protocol Violation	**1**	**4**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Total	Total of all reporting groups

Baseline Measures

	Pemetrexed + Carboplatin	Etoposide + Carboplatin	Total
Overall Participants Analyzed [Units: Participants]	**453**	**455**	**908**
Age, Customized [Units: Participants]			
<=65 years	**267**	**275**	**542**
>65 years	**186**	**180**	**366**
Gender [Units: Participants]			
Female	**128**	**125**	**253**
Male	**325**	**330**	**655**
Region of Enrollment [Units: Participants]			
United States	**92**	**83**	**175**
Portugal	**9**	**7**	**16**
Taiwan	**11**	**12**	**23**
Greece	**7**	**8**	**15**
Spain	**16**	**21**	**37**
Russian Federation	**30**	**16**	**46**
Italy	**7**	**8**	**15**
India	**12**	**14**	**26**
France	**19**	**10**	**29**
Australia	**21**	**19**	**40**
South Africa	**0**	**1**	**1**

Netherlands	**17**	**17**	**34**
China	**14**	**18**	**32**
Korea, Republic of	**17**	**15**	**32**
Turkey	**15**	**13**	**28**
Austria	**5**	**14**	**19**
United Kingdom	**16**	**18**	**34**
Hungary	**19**	**13**	**32**
Argentina	**2**	**6**	**8**
Belgium	**12**	**17**	**29**
Brazil	**4**	**7**	**11**
Poland	**29**	**34**	**63**
Romania	**20**	**23**	**43**
Germany	**58**	**59**	**117**
New Zealand	**1**	**2**	**3**
Eastern Cooperative Oncology Group Performance Status [1] [Units: Participants]			
0 - Fully Active	**133**	**121**	**254**
1 - Ambulatory, Restricted Strenuous Activity	**265**	**277**	**542**
2 - Ambulatory, No Work Activities	**54**	**55**	**109**
3 - Partially Confined to Bed, Limited Self Care	**1**	**0**	**1**
Not Reported	**0**	**2**	**2**
[1] Classifies patients according to their functional impairment. Scores range from 0 (Fully Active) to 5 (Death).			
History of Brain Metastases [Units: Participants]			
No	**410**	**412**	**822**
Yes	**43**	**41**	**84**

Not Reported	**0**	**2**	**2**
Race/Ethnicity [Units: Participants]			
Caucasian	**391**	**379**	**770**
East Asian	**43**	**49**	**92**
West Asian	**12**	**12**	**24**
African	**5**	**8**	**13**
Hispanic	**1**	**5**	**6**
Aboriginal and/or Torres Strait Islander	**0**	**2**	**2**
Native American	**1**	**0**	**1**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Survival [Time Frame: baseline to date of death from any cause (up to 19.6 months)]

Measure Type	Primary
Measure Title	Overall Survival
Measure Description	Overall survival is the duration from enrollment to death. For patients who are alive, overall survival is censored at the last contact.
Time Frame	baseline to date of death from any cause (up to 19.6 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Number of participants with events. In the pemetrexed+carboplatin group, 242 participants were censored. In the etoposide+carboplatin group, 288 participants were censored.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	Etoposide + Carboplatin
Participants Analyzed [Units: Participants]	**211**	**167**
Overall Survival [Units: Months] Median (95% Confidence Interval)	**8.1** **(7.3 to 9.1)**	**10.6** **(9.7 to 11.6)**

Statistical Analysis 1 for Overall Survival

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.01
Hazard Ratio (HR) [4]	1.56
95% Confidence Interval	1.27 to 1.92

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Overall Survival (Subgroups) [Time Frame: baseline to date of death from any cause (up to 19.6 months)]

Measure Type	Secondary
Measure Title	Overall Survival (Subgroups)
Measure Description	The effects of individual baseline factors (sex, race, Eastern Cooperative Oncology Group (ECOG) performance, region, lactate dehydrogenase (LDH), age, number of metastatic sites, and history of brain metastases) on overall survival are reported. For two subgroups - LDH<=upper limit of normal and brain metastases=yes, the upper limits of the 95% confidence interval were not calculable for the etoposide+carboplatin group - instead the number of participants in these two subgroups are presented as a post-hoc outcome measure.
Time Frame	baseline to date of death from any cause (up to 19.6 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Number of randomized participants.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	Etoposide + Carboplatin
Participants Analyzed [Units: Participants]	**453**	**455**
Overall Survival (Subgroups) [Units: Months] Median (95% Confidence Interval)		
Sex: Male (n=325, n=330)	**8.2** **(7.2 to 9.1)**	**10.4** **(9.3 to 11.5)**
Sex: Female (n=128, n=125)	**8.1** **(7.2 to 9.7)**	**11.6** **(10.3 to 13.0)**
Race: Caucasian (n=391, n=379)	**8.2** **(7.6 to 9.4)**	**11.2** **(9.9 to 12.0)**
Race: Non-Caucasian (n=62, n=76)	**7.1** **(5.7 to 9.1)**	**8.7** **(7.2 to 14.9)**
ECOG: 0 or 1 (n=398, n=398)	**8.5** **(7.8 to 9.4)**	**11.3** **(10.1 to 12.0)**
ECOG: 2 (n=54, n=55)	**6.2** **(3.7 to 7.3)**	**5.2** **(3.9 to 9.5)**
Region: United States (n=92, n=83)		

	8.1 (7.3 to 9.8)	**11.3 (9.3 to 12.9)**
Region: European Union (n=279, n=278)	**8.5 (7.2 to 9.7)**	**11.2 (9.5 to 12.9)**
Region: Intercontinential Region (n=82, n=94)	**7.2 (6.1 to 8.6)**	**9.9 (8.5 to 11.9)**
LDH: >Upper Limit of Normal (n=276, n=273)	**7.2 (6.5 to 8.3)**	**9.3 (8.0 to 10.4)**
Age: <= 65 years (n=267, n=275)	**8.4 (7.5 to 9.7)**	**11.5 (10.3 to 12.9)**
Age: >65 years (n=186, n=180)	**7.7 (7.1 to 9.0)**	**9.7 (8.7 to 11.3)**
Number Metastatic Sites: <=2 (n=172, n=204)	**10.0 (8.6 to 13.5)**	**11.5 (10.1 to 13.2)**
Number Metastatic Sites: >=3 (n=273, n=246)	**7.7 (7.2 to 8.2)**	**10.3 (9.3 to 11.3)**
History of Brain Metastases: No (n=410, n=412)	**8.2 (7.3 to 9.1)**	**10.6 (9.5 to 11.6)**

Statistical Analysis 1 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Sex: Male

Statistical Analysis 2 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.023

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Sex: Female

Statistical Analysis 3 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Race: Caucasian.

Statistical Analysis 4 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.030

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Race: Non-Caucasian.

Statistical Analysis 5 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for ECOG (Eastern Cooperative Oncology Group) Performance Status: 0 or 1.

Statistical Analysis 6 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.519

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for ECOG (Eastern Cooperative Oncology Group) Performance Status: 2.

Statistical Analysis 7 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank

P Value [3]	0.084

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Region: United States.

Statistical Analysis 8 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Region: European Union.

Statistical Analysis 9 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.003

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Region: Intercontinental Region.

Statistical Analysis 10 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.005

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for LDH (lactate dehydrogenase): >Upper Limit of Normal.

Statistical Analysis 11 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Age: <=65 years.

Statistical Analysis 12 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.013

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	

	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Age: >65 years.

Statistical Analysis 13 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.092

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Number Metastatic Sites: <=2.

Statistical Analysis 14 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for Number Metastatic Sites: >=3.

Statistical Analysis 15 for Overall Survival (Subgroups)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value for History of Brain Metastases: No.

3. Secondary: Progression Free Survival [Time Frame: baseline to measured progressive disease (up to 14.7 months)]

Measure Type	Secondary
Measure Title	Progression Free Survival

Measure Description	The period from study entry until disease progression, death or date of last contact.
Time Frame	baseline to measured progressive disease (up to 14.7 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All randomized participants. Number of participants censored: 113 in Pemetrexed+Carboplatin; 150 in Etoposide+Carboplatin.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	**Etoposide + Carboplatin**
Participants Analyzed [Units: Participants]	**453**	**455**
Progression Free Survival [Units: Months] Median (95% Confidence Interval)	**3.8** **(3.5 to 4.2)**	**5.4** **(5.2 to 5.7)**

No statistical analysis provided for Progression Free Survival

4. Secondary: Change From Baseline to Each Cycle in Functional Assessment of Cancer Therapy – Lung (FACT-L) [Time Frame: baseline and 6 cycles (21-day cycles)]

Measure Type	Secondary
Measure Title	Change From Baseline to Each Cycle in Functional Assessment of Cancer Therapy – Lung (FACT-L)
Measure Description	FACT-L measures following domains of health-related quality of life (HR-QL): physical well-being, social/family well-being, emotional well-being, functional well-being, and additional concerns of lung cancer. Total scores range from 0 to 136, with higher scores representing better HR-QL. A clinically meaningful change is considered to be 5 points.
Time Frame	baseline and 6 cycles (21-day cycles)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of randomized participants with baseline and non-missing value at respective cycle.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	**Etoposide + Carboplatin**
	384	**383**

Participants Analyzed [Units: Participants]		
Change From Baseline to Each Cycle in Functional Assessment of Cancer Therapy – Lung (FACT-L) [Units: Units on a scale] Mean (Standard Deviation)		
Baseline (n=384, n=383)	**87.42 (15.40)**	**87.79 (16.63)**
Cycle 1 Change from Baseline (n=270, n=275)	**-0.22 (12.48)**	**1.55 (11.11)**
Cycle 2 Change from Baseline (n=283, n=310)	**0.17 (13.72)**	**1.73 (12.73)**
Cycle 3 Change from Baseline (n=225, n=277)	**0.06 (14.61)**	**1.70 (13.98)**
Cycle 4 Change from Baseline (n=199, n=259)	**-0.14 (15.28)**	**1.69 (13.42)**
Cycle 5 Change from Baseline (n=140, n=203)	**0.27 (16.34)**	**1.94 (14.06)**
Cycle 6 Change from Baseline (n=98, n=146)	**0.34 (17.56)**	**3.73 (14.97)**

No statistical analysis provided for Change From Baseline to Each Cycle in Functional Assessment of Cancer Therapy – Lung (FACT-L)

5. Secondary: Overall Survival (Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes) [Time Frame: baseline to date of death due to any cause (up to 19.6 months)]

Measure Type	Secondary
Measure Title	Overall Survival (Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes)
Measure Description	The effects of individual baseline factors (lactate dehydrogenase (LDH) and history of brain metastases) on overall survival are reported. The Upper Limits of the 95% Confidence Intervals were not calculable for these factors in the Etoposide+Carboplatin group. The number of participants in these subgroup are instead presented as a Post-Hoc Outcome Measure.
Time Frame	baseline to date of death due to any cause (up to 19.6 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The upper limit of the 95% Confidence Intervals (CI) were not calculable for these two subgroups in the etoposide+carboplatin group so medians and lower limits of the 95% CI are not presented. A post-hoc outcome measure table provides the number of participants in each subgroup.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	**Etoposide + Carboplatin**
Participants Analyzed [Units: Participants]	**0**	**0**
Overall Survival (Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes) [Units: Months] Median (95% Confidence Interval)		

No statistical analysis provided for Overall Survival (Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes)

6. Post-Hoc: Number of Participants in Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes [Time Frame: baseline to date of death due to any cause (up to 19.6 months)]

Measure Type	Post-Hoc
Measure Title	Number of Participants in Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes
Measure Description	Number of participants with Low Density Lipoprotein <=upper limit of normal and the number of participants with a history of brain metastases. This post-hoc outcome replaces the one for Overall Survival (Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes).
Time Frame	baseline to date of death due to any cause (up to 19.6 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Number of randomized participants.

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Carboplatin	**Etoposide + Carboplatin**
Participants Analyzed [Units: Participants]	**453**	**455**

Number of Participants in Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes [Units: Participants]		
LDH: <=Upper Limit of Normal	**167**	**169**
History of Brain Metastases: Yes	**43**	**41**

No statistical analysis provided for Number of Participants in Subgroups: LDH<=Upper Limit of Normal and History of Brain Metastases=Yes

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Pemetrexed + Carboplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles (Participants who received at least one dose of study drug)
Etoposide + Carboplatin	Etoposide: 100 mg/m2, intravenous (IV), days 1-3 x 6 cycles Carboplatin: Area under the curve (AUC) 5, intravenous (IV), every 21 days x 6 cycles.

	(Participants who received at least one dose of study drug)

Other Adverse Events

	Pemetrexed + Carboplatin	Etoposide + Carboplatin
Total, other (not including serious) adverse events		
# participants affected	**425**	**438**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**135/433 (31.18%)**	**155/447 (34.68%)**
# events	**175**	**200**
Leukopenia † 1		
# participants affected / at risk	**33/433 (7.62%)**	**86/447 (19.24%)**
# events	**67**	**179**
Neutropenia † 1		
# participants affected / at risk	**82/433 (18.94%)**	**252/447 (56.38%)**
# events	**141**	**524**
Thrombocytopenia † 1		
# participants affected / at risk	**61/433 (14.09%)**	**94/447 (21.03%)**
# events	**117**	**151**
Cardiac disorders		
Coronary artery disease † 1		
# participants affected / at risk	**23/433 (5.31%)**	**24/447 (5.37%)**
# events	**23**	**24**
Endocrine disorders		
Hypothyroidism † 1		
# participants affected / at risk	**26/433 (6.00%)**	**12/447 (2.68%)**
# events	**26**	**12**

Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**24/433 (5.54%)**	**27/447 (6.04%)**
# events	**26**	**27**
Constipation † 1		
# participants affected / at risk	**135/433 (31.18%)**	**124/447 (27.74%)**
# events	**165**	**155**
Diarrhoea † 1		
# participants affected / at risk	**62/433 (14.32%)**	**59/447 (13.20%)**
# events	**72**	**69**
Dyspepsia † 1		
# participants affected / at risk	**24/433 (5.54%)**	**24/447 (5.37%)**
# events	**24**	**26**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**28/433 (6.47%)**	**21/447 (4.70%)**
# events	**28**	**21**
Nausea † 1		
# participants affected / at risk	**166/433 (38.34%)**	**159/447 (35.57%)**
# events	**261**	**267**
Stomatitis † 1		
# participants affected / at risk	**22/433 (5.08%)**	**15/447 (3.36%)**
# events	**23**	**19**
Vomiting † 1		
# participants affected / at risk	**71/433 (16.40%)**	**72/447 (16.11%)**
# events	**96**	**106**
General disorders		
Asthenia † 1		
# participants affected / at risk	**48/433 (11.09%)**	**43/447 (9.62%)**

# events	55	51
Chest pain [†1]		
# participants affected / at risk	98/433 (22.63%)	114/447 (25.50%)
# events	104	127
Fatigue [†1]		
# participants affected / at risk	153/433 (35.33%)	182/447 (40.72%)
# events	177	221
Mucosal inflammation [†1]		
# participants affected / at risk	22/433 (5.08%)	26/447 (5.82%)
# events	26	33
Oedema peripheral [†1]		
# participants affected / at risk	38/433 (8.78%)	33/447 (7.38%)
# events	40	41
Pyrexia [†1]		
# participants affected / at risk	26/433 (6.00%)	49/447 (10.96%)
# events	29	59
Investigations		
Haemoglobin decreased [†1]		
# participants affected / at risk	22/433 (5.08%)	15/447 (3.36%)
# events	24	15
Weight decreased [†1]		
# participants affected / at risk	60/433 (13.86%)	50/447 (11.19%)
# events	64	53
Metabolism and nutrition disorders		
Anorexia [†1]		
# participants affected / at risk	108/433 (24.94%)	98/447 (21.92%)
# events	130	120
Diabetes mellitus [†1]		

# participants affected / at risk	45/433 (10.39%)	44/447 (9.84%)
# events	45	44
Hypercholesterolaemia † 1		
# participants affected / at risk	45/433 (10.39%)	47/447 (10.51%)
# events	45	47
Hyperglycaemia † 1		
# participants affected / at risk	23/433 (5.31%)	18/447 (4.03%)
# events	25	26
Hypokalaemia † 1		
# participants affected / at risk	23/433 (5.31%)	17/447 (3.80%)
# events	24	18
Hyponatraemia † 1		
# participants affected / at risk	25/433 (5.77%)	27/447 (6.04%)
# events	31	37
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	23/433 (5.31%)	38/447 (8.50%)
# events	24	43
Back pain † 1		
# participants affected / at risk	61/433 (14.09%)	81/447 (18.12%)
# events	67	91
Bone pain † 1		
# participants affected / at risk	15/433 (3.46%)	26/447 (5.82%)
# events	16	26
Musculoskeletal pain † 1		
# participants affected / at risk	23/433 (5.31%)	31/447 (6.94%)
# events	23	33
Pain in extremity † 1		
# participants affected / at risk	29/433 (6.70%)	17/447 (3.80%)

# events	30	18
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	30/433 (6.93%)	41/447 (9.17%)
# events	34	43
Headache † 1		
# participants affected / at risk	49/433 (11.32%)	61/447 (13.65%)
# events	62	78
Psychiatric disorders		
Anxiety † 1		
# participants affected / at risk	45/433 (10.39%)	36/447 (8.05%)
# events	45	36
Depression † 1		
# participants affected / at risk	41/433 (9.47%)	38/447 (8.50%)
# events	41	38
Insomnia † 1		
# participants affected / at risk	72/433 (16.63%)	68/447 (15.21%)
# events	78	78
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	69/433 (15.94%)	71/447 (15.88%)
# events	69	71
Cough † 1		
# participants affected / at risk	210/433 (48.50%)	221/447 (49.44%)
# events	218	239
Dysphonia † 1		
# participants affected / at risk	49/433 (11.32%)	42/447 (9.40%)
# events	50	43

Dyspnoea † 1		
# participants affected / at risk	**178/433 (41.11%)**	**182/447 (40.72%)**
# events	**189**	**200**
Haemoptysis † 1		
# participants affected / at risk	**33/433 (7.62%)**	**32/447 (7.16%)**
# events	**34**	**34**
Productive cough † 1		
# participants affected / at risk	**31/433 (7.16%)**	**20/447 (4.47%)**
# events	**31**	**21**
Skin and subcutaneous tissue disorders		
Alopecia † 1		
# participants affected / at risk	**27/433 (6.24%)**	**156/447 (34.90%)**
# events	**29**	**158**
Rash † 1		
# participants affected / at risk	**23/433 (5.31%)**	**25/447 (5.59%)**
# events	**24**	**36**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**180/433 (41.57%)**	**172/447 (38.48%)**
# events	**181**	**175**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

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.

The agreement is:

- ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.
- ☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Organization: Eli Lilly and Company
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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Socinski MA, Smit EF, Lorigan P, Konduri K, Reck M, Szczesna A, Blakely J, Serwatowski P, Karaseva NA, Ciuleanu T, Jassem J, Dediu M, Hong S, Visseren-Grul C, Hanauske AR, Obasaju CK, Guba SC, Thatcher N. Phase III study of pemetrexed plus carboplatin compared with etoposide plus carboplatin in chemotherapy-naive patients with extensive-stage small-cell lung cancer. J Clin Oncol. 2009 Oct 1;27(28):4787-92. doi: 10.1200/JCO.2009.23.1548.

Responsible Party:	Chief Medical Officer, Eli Lilly
ClinicalTrials.gov Identifier:	NCT00363415 History of Changes
Other Study ID Numbers:	9691
	H3E-MC-JMHO
Study First Received:	August 10, 2006
Results First Received:	June 5, 2009
Last Updated:	October 20, 2009
Health Authority:	European Union: European Medicines Agency
	United States: Food and Drug Administration