ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Trial record **1 of 1** for: H3E-XM-S113

Previous Study | Return to List | Next Study

Pemetrexed and Cisplatin as Treatment in Small Cell Lung Cancer

This study has been terminated.

(Terminated due to lack of efficacy)

Sponsor:
Eli Lilly and Company

Information provided by:
Eli Lilly and Company

ClinicalTrials.gov Identifier:
NCT00475657

First received: May 16, 2007
Last updated: May 22, 2009
Last verified: May 2009
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: March 31, 2009

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Small Cell Lung Cancer
Interventions:	

	Drug: pemetrexed Drug: cisplatin

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
No text entered.

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Participant Flow: Overall Study

	Pemetrexed + Cisplatin
STARTED	**5**
COMPLETED	**1**
NOT COMPLETED	**4**
Death	**1**
Sponsor's Decision	**3**

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 + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Baseline Measures

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**5**
Age [units: years] Mean (Standard Deviation)	**66.6 (5.9)**
Gender [units: participants]	
Female	**0**
Male	**5**

Region of Enrollment [units: participants]	
Spain	**5**
Race/Ethnicity [units: participants]	
Caucasian	**5**
Height [units: centimeters] Mean (Standard Deviation)	**163.9 (4.2)**
Weight [units: kilograms] Mean (Standard Deviation)	**76.0 (5.9)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Overall Response Rate [Time Frame: baseline to measured progressive disease]

Measure Type	Primary
Measure Title	Overall Response Rate
Measure Description	Trial terminated - results not analyzed
Time Frame	baseline to measured progressive disease
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.
No text entered.

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**0**
Overall Response Rate [units: participants]	

No statistical analysis provided for Overall Response Rate

2. Secondary: Overall Survival [Time Frame: baseline to date of death from any cause]

Measure Type	Secondary
Measure Title	Overall Survival
Measure Description	Trial terminated - results not analyzed
Time Frame	baseline to date of death from any cause
Safety Issue	Yes

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 + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**0**
Overall Survival [units: participants]	

No statistical analysis provided for Overall Survival

3. Secondary: Progression Free Survival [Time Frame: baseline to measured progressive disease]

Measure Type	Secondary
Measure Title	Progression Free Survival
Measure Description	Trial terminated - results not analyzed
Time Frame	baseline to measured progressive disease

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.
No text entered.

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**0**
Progression Free Survival [units: participants]	

No statistical analysis provided for Progression Free Survival

4. Secondary: Duration of Response [Time Frame: time of response to progressive disease]

Measure Type	Secondary
Measure Title	Duration of Response
Measure Description	Trial terminated - results not analyzed

Time Frame	time of response to progressive disease
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.
No text entered.

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**0**
Duration of Response [units: months] Mean (Standard Deviation)	

No statistical analysis provided for Duration of Response

5. Secondary: Stable Disease Rate [Time Frame: baseline to measured progressive disease]

Measure Type	Secondary

Measure Title	Stable Disease Rate
Measure Description	Trial terminated - results not analyzed
Time Frame	baseline to measured progressive disease
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.
No text entered.

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Measured Values

	Pemetrexed + Cisplatin
Overall Participants [units: participants]	**0**
Stable Disease Rate [units: participants]	

No statistical analysis provided for Stable Disease Rate

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Serious Adverse Events

	Pemetrexed + Cisplatin
Total, serious adverse events	
# participants affected	**2**
Gastrointestinal disorders	
Diarrhoea † 1	
# participants affected / at risk	**1/5 (20.00%)**
# events	**1**
Dysphagia † 1	
# participants affected / at risk	**1/5 (20.00%)**
# events	**1**
General disorders	
Pyrexia † 1	
# participants affected / at risk	**1/5 (20.00%)**
# events	**1**
Renal and urinary disorders	
Renal failure acute † 1	

# participants affected / at risk	**1/5 (20.00%)**
# events	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

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	0

Reporting Groups

	Description
Pemetrexed + Cisplatin	Pemetrexed: 500 mg/m2, intravenous (IV), every 21 days x 6 cycles Cisplatin: 75 mg/m2, intravenous (IV), every 21 days x 6 cycles

Other Adverse Events

	Pemetrexed + Cisplatin
Total, other (not including serious) adverse events	
# participants affected	**5**
Blood and lymphatic system disorders	
Anaemia † 1	

# participants affected / at risk	1/5 (20.00%)
# events	1
Leukopenia † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Lymphopenia † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Endocrine disorders	
Inappropriate antidiuretic hormone secretion † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Gastrointestinal disorders	
Nausea † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
General disorders	
Asthenia † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Investigations	
Gamma-glutamyltransferase increased † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Blood creatine increased † 1	
# participants affected / at risk	1/5 (20.00%)
# events	1
Metabolism and nutrition disorders	

Hypokalaemia † 1	
# participants affected / at risk	**1/5 (20.00%)**
# events	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 10.1

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
On the advice of an independent monitoring board, this trial was stopped early due to lack of efficacy of the combination pemetrexed/carboplatin for small cell lung cancer.

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:

Name/Title: Chief Medical Officer
Organization: Eli Lilly and Company
phone: 1-800-545-5979

Responsible Party:	Chief Medical Officer, Eli Lilly
ClinicalTrials.gov Identifier:	NCT00475657 History of Changes
Other Study ID Numbers:	11473
	H3E-XM-S113
Study First Received:	May 16, 2007
Results First Received:	March 31, 2009
Last Updated:	May 22, 2009
Health Authority:	Spain: Spanish Agency of Medicines