Comparing Common Safety Outcomes in Locally Advanced or Metastatic Non-small Cell Lung Cancer Patients Treated with Various First-line Platinum-containing Chemotherapy Combination Regimens (H3E-MC-B026)

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Study Finalised

Administrative details

EU PAS number

EUPAS10688

Study ID

27984

DARWIN EU® study

No

Study countries

United States

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

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Primary lead investigator

Sangmi Kim

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 05/02/2015

Actual: 05/02/2015

Study start date
Planned: 15/01/2016

Actual: 15/01/2016

Date of final study report
Planned: 31/05/2016

Actual: 01/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

H3E-MC-B026 AE in NSCLC Platinum Combos_Redacted.pdf(847.17 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the safety outcomes among Stage IIIB/IV NSCLC patients treated with Pemetrexed+Cisplatin, Pemetrexed+Carboplatin, Pemetrexed+Bevacizumab+Carboplatin, Paclitaxel+Carbopltain, Paclitaxel+Bevacizumab+Carboplatin, or Docetaxel+Carboplatin

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BEVACIZUMAB

CARBOPLATIN

CISPLATIN

DOCETAXEL

PEMETREXED

PACLITAXEL

Population studied

Short description of the study population

Stage IIIB/IV NSCLC patients who received one of the selected chemotherapy regimens on or after the date of NSCLC diagnosis. From 26 September 2008 (the date that Pemetrexed was first approved for first-line treatment of NSCLC by the FDA in the US) and 30 November 2014 (1 month before the last date that the data are available in the database), among all patients with only one primary tumor type and valid age information, those who meet the following criteria were included in the study:

1) Patients were diagnosed with lung cancer as a primary cancer (at least one ICD-9-CM code indicating lung cancer, or a TUMOR TYPE value of “Lung Cancer”) with at least an ICD-O-3 code indicating non-small cell histology (Howlader et al. 2014), or a cancer subtype recorded as “NSCLC” records in the IMS Oncology electronic medical records (EMR); and

2) The staging information indicating locally advanced or metastatic disease
3) Patients initiated the first-line treatment including Pem/Cis, Pem/Carbo, Pem/Bev/Carbo,Pac/Carbo, Pac/Bev/Carbo, or Doc/Carbo after the lung cancer diagnosis. The date of any of the above first-line treatment initiation is the index date; and
4) Patients must be 18 years of age or older on the index date; and
5) Patient’s oncology practice must be stable between the index date and end of record in the database, or 31 December 2014, whichever comes first.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Non-small cell lung cancer patients

Estimated number of subjects

2600

Study design details

Outcomes

To estimate the crude incidence proportions and rates of the safety outcomes among the NSCLC patients receiving 1st line treatment with selected chemotherapy regimens, to describe demographic and clinical characteristics of each treatment group, if sample size allows, to compare the safety outcomes between the treatment groups by hazard ratio by adjusting patient and clinical characteristics. If sample size allows, to conduct subgroup analyses to further examine the safety profiles of the NSCLC patients treated with the regimens in those who were below 70 and who were 70 years or older.

Data analysis plan

The primary analysis of this protocol is to describe the incident safety outcomes after index date in patients who were administered at least one of the selected chemotherapy regimens. If sample size allows, adjusted incidence rates, rate difference and hazard ratios will be estimated among the comparable patients with the application of the propensity score stratification method.

Documents

Study results

B026 PASS(1_Redacted.pdf(375.69 KB)

Data management

Data sources

Data source(s), other

IMS Oncology United States

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown