Safety Profile of Pemetrexed+Carboplatin AUC5 and Pemetrexed+Carboplatin AUC6 for Patients with Non-Small Cell Lung Cancer (H3E-MC-B025)

First published: 21/04/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9318

Study ID

27980

DARWIN EU® study

No

Study countries

☐ United States

Study description

Pemetrexed in combination with carboplatin chemotherapy (Pem/Carbo) is widely recognized and endorsed by local and regional treatment guidelines used in clinical practice to treat patients with nonsquamous Non Small Cell Lung Cancer (NSCLC) in various countries around the world. There is a lack of information summarizing the safety profile of patients treated with this combination in real-world settings, which is in need by health care professionals. The purpose of this study is to evaluate the safety profiles of NSCLC patients treated with Pem/Carbo AUC5 and Pem/Carbo AUC6.A retrospective cohort study is proposed. The study will use information from a United States database that contains oncology clinics electronic medical records, combined with medical claims and pharmacy data, to assess the incidence of haematological and non-haematological safety outcomes among NSCLC patients treated with Pem/Carbo AUC5 relative to Pem/Carbo AUC6.

Study status

Finalised

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sangmi Kim

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/11/2014

Actual: 06/04/2015

Study start date

Planned: 20/04/2015

Actual: 27/04/2015

Date of final study report

Planned: 31/12/2015

Actual: 05/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY231514 PASS Protocol (Pem-Carbo) ENCePP.pdf(535.63 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:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The purpose of this study is to evaluate the safety profiles of Non Small Cell Lung Cancer (NSCLC) patients treated with Pemetrexed /Carboplatin (Pem/Carbo) AUC5 and Pem/Carbo AUC6.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

PEMETREXED

CARBOPLATIN

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Non-small cell lung cancer (NSCLC) patients with evidence of initiating Pem/Carbo AUC5 or Pem/Carbo AUC6 on or after the date of NSCLC diagnosis. During 04 February 2004 (the date that Pemetrexed was first approved by FDA in the US) and 31 May 2014 (30 days before the last date that the data are available in the database), among all patients
with only 1 primary tumour type and valid age information, those who meet the following criteria will be included in the study:
1) Patients were diagnosed with lung cancer as a primary cancer (at least one ICD-9-CM code in 162.2, 162.3, 162.4, 162.5, 162.8, or162.9, or a TUMOR TYPE value of
“Lung Cancer”), excluding those who had a small cell histology (ICD-O-3 code 8002, 8041-8045, or a cancer subtype recorded as “SCLC” [small cell lung cancer] in the
IMS Oncology EMR); and
2) Patients initiated the Pem/Carbo AUC5 or Pem/Carbo AUC6 after the lung cancer diagnosis. The date of Pem/Carbo AUC5 or Pem/Carbo AUC6 initiation is the index date, excluding those who started on Pemetrexed/Carboplatin/Bevacizumab and then switched to Pem/Carbo AUC5 or Pem/Carbo AUC6 and those who started on Pem/Carbo AUC5 or Pem/Carbo AUC6 and then switched to Pemetrexed/Carboplatin/Bevacizumab; and
3) Patients must be 18 years of age or older on the index date, have valid gender and weight information, at least one non-missing serum creatinine test result during the period from 7 days prior to the index date until 7 days after the index date, and valid dose record for the index carboplatin prescription; and
4) Patient’s oncology practice must be stable between the index date and end of record in the database, or 30 June 2014, whichever 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

700

Study design details

Outcomes

Primary objectives are, in NSCLC patients treated with Pem/Carbo AUC5 or Pem/Carbo AUC6,1) To describe patient demographic and clinical characteristics.2) To estimate the crude incidence proportions and incidence rates of the safety outcomes.3) If data allow, to estimate the incidence rate, rate difference, and HR of safety outcomes in adjusted analyses. If data allow, the secondary objectives include conducing subgroup analysis to further examine the safety profiles of the NSCLC patients treated with Pem/Carbo AUC5 or Pem/Carbo AUC6 in those who were below 70 and who were 70 years or older

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Data analysis plan

Analyses will be conducted in a cohort of NSCLC patients treated with Pem/Carbo AUC5 or Pem/Carbo AUC6, in IMS Oncology between 04 February 2004 and 30 June 2014.Descriptive statistics will be used to describe baseline demographic and clinical characteristics of patients treated with Pem/Carbo AUC5 or Pem/Carbo AUC6. Crude incidence rates of safety outcomes among patients treated with Pem/Carbo AUC5 or Pem/Carbo AUC6 will be calculated. The frequency and incidence rate of the safety outcomes with 95% CIs will be estimated based on the first occurrence of these safety events.If data allow, the adjusted incidence rates, rate difference, and HR of treatment-emergent safety outcomes will be estimated. Propensity score stratification will be used to adjust for differences in the distribution of baseline characteristics. Cox regression models will be used to compare time-to-event in the Pem/Carbo AUC5 and Pem/Carbo AUC6 cohorts. All analysis will be carried out using SAS (version 9.2).

Documents

Study results

B025 PASS (1.0)_Redacted.pdf(405.69 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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