An Observational Study to Estimate Incidence Rates of Heart Failure Among US Racial and Ethnic Minority Patients With Multiple Myeloma Treated or Not Treated With Carfilzomib

First published: 10/08/2019

Last updated: 09/12/2020

Study Finalised

Administrative details

EU PAS number

EUPAS30748

Study ID

38535

DARWIN EU® study

No

Study countries

☐ United States

Study description

On 14 June 2018, Amgen submitted to the FDA a labeling supplement which proposed an update to the Kyprolis US Prescribing Information indicating that the risk of developing cardiac failure is higher among Asian patients. This increased risk was identified following analysis of data from Amgen sponsored clinical trials and postmarketing reports. On 14 December 2018, the FDA issued a complete response letter, which highlighted the lack of evidence to support that there is an increased risk of cardiac failure in US Asian patients. In addition, based on the submission of this supplement, the Agency stated the concern of the potential differential risk of cardiac failure among racial and ethnic minorities. To address these issues, Amgen agreed to conduct a postmarketing requirement in the form of an observational study to estimate incidence rates of heart failure among US racial and ethnic minority patients with multiple myeloma treated or not treated with carfilzomib.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2019

Actual: 15/02/2019

Study start date

Planned: 01/09/2019

Actual: 01/09/2019

Data analysis start date

Planned: 01/10/2019

Actual: 01/10/2019

Date of final study report

Planned: 30/06/2020

Actual: 17/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20190012_Public Redacted Protocol Amend 1 English.pdf(846.34 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

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:

1. Estimate the incidence rates of cardiac failure in US racial and ethnic populations of patients with multiple myeloma treated with carfilzomib2. Estimate the incidence rates of cardiac failure in US racial and ethnic populations of patients with multiple myeloma not treated with carfilzomib

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

KYPROLIS

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Patients who satisfied the following key criteria were eligible:

1. Multiple myeloma diagnosis, as determined utilizing an algorithm based upon presence of a combination of ICD-9-CM and ICD-10-CM diagnosis codes, Current Procedural Terminology codes for diagnosis tests or National Drug Codes and Healthcare Common Procedure Coding System codes for treatments
2. Age ≥ 18 years.
3. Receipt of carfilzomib or other multiple myeloma treatments in at least 1 LOT
4. Continuously enrolled in medical and pharmacy insurance coverage for 12 months before the treatment index.

Exclusion Criteria

Patients with missing or unknown race/ethnicity variable or evidence of renal transplant or dialysis were excluded.

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

Multiple myeloma patients

Estimated number of subjects

3689

Study design details

Outcomes

The primary outcome is the incidence rate of heart failure in the US white, black, Asian, and Hispanic multiple myeloma patients treated with carfilzomib-containing or carfilzomib-free drug regimens.

Data analysis plan

The incidence rate of heart failure will be estimated for US racial and ethnic minority multiple myeloma patients treated with carfilzomib-containing or carfilzomib-free regimens. As exploratory analysis, risk for heart failure will be compared between myeloma patients treated with carfilzomib-containing vs. carfilzomib-free regimens among whites and blacks in the US.

Documents

Study results

20190012_ Observational Research Study Report Published Report.pdf(9.41 MB)

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

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

No