Risk factors for cardiac events in carfilzomib-treated patients in the Marketscan database (20160186)

First published: 19/05/2016

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19462

EU PAS number

EUPAS13518

Study ID

19462

DARWIN EU® study

No

Study countries

☐ United States

Study description

Descriptive analysis comparing the characteristics of carfilzomib-treated patients who do and do not have claims for a defined cardiac event in the Marketscan administrative claims database. Exploratory objectives will compare incidence of defined cardiac events in carfilzomib-treated patients to multiple myeloma patients 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.

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: 31/05/2016

Actual: 31/05/2016

Study start date

Planned: 31/05/2016

Actual: 31/05/2016

Data analysis start date

Planned: 31/05/2016

Actual: 15/06/2016

Date of final study report

Planned: 15/06/2017

Actual: 08/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

Protocol for Marketscan CVD Events MM _05022016_final.pdf(634.73 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:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The aim of this observational study is to describe the differences between carfilzomib-treated Multiple Myeloma (MM) patients who do and do not have cardiac events in the Marketscan administrative database in the United States.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective cohort study

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

Newly diagnosed multiple myeloma patients treated with carfilzomib beginning in January 1, 2005 through June 30, 2015.

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

350

Study design details

Outcomes

Aim 1: Identify and estimate the incidence rate of defined cardiac events in carfilzomib-treated MM patients during the treatment period and 30 day period after termination of treatment.Aim 2: Compare the demographic and clinical characteristics of carfilzomib-treated patients with and without the occurrence of defined cardiac events, Aim 1: Assess defined cardiac event incidence and association by cumulative duration of carfilzomib treatment and by line of

treatment that carfilzomib is administered Exploratory Objective: Compare the incidence rates of defined cardiac events from the carfilzomib-treated cohort to non-carfilzomib-treated cohort.

Data analysis plan

The primary outcomes of interest in this study will be any cardiac events. Cardiac events will be defined as hypertension including malignant hypertension, heart failure, ischemic heart disease including acute myocardial infarction, cardiac arrhythmias and conduction disorders, or cardiomyopathy. Incidence rates for each type of defined cardiac event will be estimated using traditional methods (eliminating those with prevalent cardiac events at treatment start date from the numerator and denominator, prevalent cardiac conditions is defined by occurrence of a claim for the cardiac events in the baseline period). A patient will be counted in the numerator of the incidence rate at the time of the first diagnosis. Patient follow up begins at treatment index and continues until first occurrence of the outcome for those experiencing an event of interest. For event-free patients, follow-up begins at treatment index and ends 30 days after the end of active carfilzomib-treatment. Explorator

Documents

Study results

Abstract 20160186_Carfilzomib_31May2017.pdf(122.9 KB)

Data management

Data sources

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