Risk Prediction, Prognosis and Management of Cardiac Events among Patients with Multiple Myeloma (20160220)

First published: 31/10/2016

Last updated: 13/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS15924

Study ID

17624

DARWIN EU® study

No

Study countries

United States

Study description

Carfilzomib (Kyprolis) is a proteasome inhibitor indicated for the treatment of patients with advanced multiple myeloma (MM). Cardiac events in patients with MM have been associated with several classes of anti-MM treatments, including chemotherapy agents, immunomodulatory drugs, and proteasome inhibitors.While data on cardiovascular (CV) safety related to carfilzomib exists, uncertainties in the real world use of carfilzomib remain. The aim of this protocol is to address gaps in the current understanding of the occurrence of cardiac events among MM patients treated with carfilzomib using a real world data source.Due to the availability of results from a completed observational study and the anticipated results from an ongoing observational study on carfilzomib exposure and cardiac events, this study has been cancelled as of 27 January 2017.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 27/03/2026

Institution

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

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: 31/10/2016

Actual: 31/10/2016

Study start date

Planned: 31/10/2016

Actual: 31/10/2016

Data analysis start date
Planned: 31/05/2017

Date of final study report
Planned: 31/05/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20160220 Protocol Ver 1.0 2016-09-13 English.pdf (606.21 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

The aim of this observational study is to describe cardiac events in carfilzomib-treated Multiple Myeloma (MM) patients using a real world data source in the Optum 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

Medicinal product name

KYPROLIS

Medical condition to be studied

Plasma cell myeloma

Population studied

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)

Estimated number of subjects

540

Study design details

Outcomes

Cardiac events in MM patients treated with carfilzomib, Subsequent treatment and prognosis of cardiac events

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Data analysis plan

Among the MM patients treated with carfilzomib, the occurrence of chart-confirmed cardiac events will be summarized overall by subtype and key comorbidity strata within the MM patient population. The frequency and percent of claims-identified events as well as those of chart-adjudicated events will be reported for each cardiac event. To describe predictors for preselected cardiac events in MM patients receiving carfilzomib, cross tabulations of confirmed cardiac events from medical chart review by treatment patterns, patient attributes, and potential cardiovascular risk factors will be presented. After assessment of univariate analyses, regression modeling will be used to evaluate the adjusted association between the potential risk factors and cardiac events.Indicators of cardiac prognosis and treatment will be described overall by line of therapy, treatment regimen, and refractory disease state. Indicators

of prognosis will include claims based measures and chart-based measures

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)

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