

# 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.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

Amgen

☐ United States

**First published:** 01/02/2024

**Last updated:** 21/02/2024

Institution

Optum

☐ Germany

**First published:** 03/01/2012

**Last updated:** 07/02/2014

Institution

Other

ENCePP partner

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

[medinfo@amgen.com](mailto: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

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### Study start date

Planned: 31/10/2016

Actual: 31/10/2016

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### **Data analysis start date**

Planned: 31/05/2017

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### **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

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### **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

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**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

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**Non-interventional study design, other**

Retrospective cohort study

## Study drug and medical condition

**Name of medicine**

KYPROLIS

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**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)

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**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

### 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

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#### **Check completeness**

Unknown

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#### **Check stability**

Unknown

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#### **Check logical consistency**

Unknown

### Data characterisation

**Data characterisation conducted**

No