

# 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

### 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

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## Study status

Finalised

# Research institutions and networks

## Institutions

Amgen

☐ United States

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

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Institution

## Contact details

### Study institution contact

Global Development Leader Amgen Inc.  
medinfo@amgen.com

Study contact

### **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

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### **Study start date**

Planned: 31/05/2016

Actual: 31/05/2016

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### **Data analysis start date**

Planned: 31/05/2016

Actual: 15/06/2016

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### **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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Data collection methods:**

Secondary use of data

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**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

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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

## Short description of the study population

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

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### 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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### Special population of interest

Other

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### Special population of interest, other

Multiple myeloma patients

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### 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.

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### **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)

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## **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**

Unknown