

# A retrospective analysis of pre-existing and acquired major adverse cardiovascular events (MACE) in a real world cohort of multiple myeloma (MM) patients treated with proteasome inhibitors

**First published:** 30/11/2016

**Last updated:** 02/06/2020

Study

Finalised

## Administrative details

### EU PAS number

EUPAS16302

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### Study ID

35617

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### DARWIN EU® study

No

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### Study countries

United States

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## Study description

The primary objectives are observational and descriptive. The purpose of the study is to estimate the incidence of CV outcomes for bortezomib- and carfilzomib- treated patients. For the exploratory objective, Kaplan Meier curves will compare time to CV event rate between the two groups- bortezomib- and carfilzomib- treated patients.

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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**

[Brigham & Women's Hospital Boston USA, Dana](#)

[Farber Institute Boston USA, Massachusetts](#)

[General Hospital Boston USA](#)

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Global Development Leader Amgen Inc.

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 31/05/2016

Actual: 11/07/2016

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**Study start date**

Planned: 30/11/2016

Actual: 30/11/2016

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**Data analysis start date**

Planned: 30/06/2019

Actual: 05/06/2019

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**Date of final study report**

Planned: 01/06/2020

Actual: 02/06/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Amgen

## Study protocol

[01.20.01 Protocol Ver 1.0 2016-08-26 English.pdf](#) (414.07 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 topic:**

Human medicinal product

Disease /health condition

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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 in the incidence of CV outcomes for bortezomib- and carfilzomib- treated patients.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Retrospective analysis

## Study drug and medical condition

**Medicinal product name**

KYPROLIS

VELCADE

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**Medical condition to be studied**

## Population studied

### **Short description of the study population**

Patients with multiple myeloma (MM) treated with proteasome inhibitors.

Patients eligible for this study will have received treatment for MM at one of the following institutions: Brigham & Women's Hospital, Dana Farber Cancer Institute, or Massachusetts General Hospital, Boston. Patient cohorts will include:

a) 400 consecutive patients treated with bortezomib with MM who have received  $\geq 1$  prior treatments, and

a) 250 consecutive patients with relapsed and/or refractory MM treated with carfilzomib, who have received  $\geq 1$  prior treatments prior to initiating carfilzomib.

### Inclusion Criteria

1. Patients with a diagnosis of MM who have received  $\geq 1$  prior treatments prior to treatment with carfilzomib or bortezomib
2. Treatment for at least 1 cycle with bortezomib (21 day cycle) or carfilzomib (28 day cycle)
3. Age  $\geq 18$  years

### Exclusion Criteria

1. Use of bortezomib or carfilzomib as first line treatment for MM (i.e. no prior treatment).
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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**

650

## Study design details

### **Outcomes**

- Incidence of MACE and extended MACE in bortezomib and carfilzomib- treated patients with MM
  - Pre-treatment cardiovascular risk profile and overall comorbidities in bortezomib and carfilzomib-treated patients with MM, Risk factors for MACE and extended MACE in MM patients: overall, bortezomib-treated, and carfilzomib- treated
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### **Data analysis plan**

For the primary endpoint, the incidence of MACE and extended MACE will be calculated separately for bortezomib- and carfilzomib- treated patients. Incidence of MACE and extended MACE will be calculated by counting incident events in the carfilzomib-treated cohort or bortezomib-treated cohort. For the secondary objective, pre-treatment cardiovascular risk profile and overall comorbidities in bortezomib- and carfilzomib-treated patients will be compared using the Fisher Exact Test for categorical data and the Student t-test for

continuous data. For the exploratory objective, risk factors for MACE and extended MACE in MM patients will be analyzed overall and for bortezomib-treated and carfilzomib-treated cohorts, separately. A generalized logistic regression model will be used to identify predictors of MACE and extended MACE.

## Documents

### Study results

[20160154 ORS20May2020\\_Redacted.pdf](#) (77.33 KB)

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## 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)

[Other](#)

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### Data sources (types), other

Retrospective cohort based on combination of EMR review, Patient Data Registry, and the National Death index

## 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