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

PURI

https://redirect.ema.europa.eu/resource/35617

EU PAS number

EUPAS16302

Study ID

35617

DARWIN EU® study

No

Study countries

United States

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.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Brigham & Women's Hospital Boston USA, Dana Farber Institute Boston USA, Massachusetts General Hospital Boston USA

Contact details

Study institution contact

Global Development Leader Amgen Inc.

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

Study start date

Planned: 30/11/2016

Actual: 30/11/2016

Data analysis start date

Planned: 30/06/2019

Actual: 05/06/2019

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

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

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

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective analysis

Study drug and medical condition

Name of medicine

KYPROLIS

VELCADE

Medical condition to be studied

Plasma cell myeloma

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 ≥ 1prior treatments, and

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

Inclusion Criteria

1. Patients with a diagnosis of MM who have received ≥ 1prior 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 ≥ 18 years

Exclusion Criteria

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

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

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

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)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No