Real-world Evidence of the Use of Carfilzomib Among Multiple Myeloma Patients in Europe Who Have Received at Least One Prior Therapy (Use of Carfilzomib In Multiple Myeloma Patients)

First published: 05/08/2019

Last updated: 14/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS30534

Study ID

40100

DARWIN EU® study

No

Study countries

Austria

Belgium

Bulgaria
France
Greece
Israel
Italy
Netherlands
Norway
Romania

Study description

With the recent addition of carfilzomib as a treatment option for multiple myeloma, no data is available yet on how the drug is being used outside of the clinical trial setting. This study will therefore provide essential data to demonstrate the real world utilization of carfilzomib in routine clinical practice, including dosage, administration schedule, regimen, duration of treatment and reason for discontinuation in Europe.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

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Institution

Multiple centres: 117 centres are involved in the study

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: 25/08/2016

Actual: 25/08/2016

Study start date

Planned: 14/03/2017

Actual: 14/03/2017

Data analysis start date

Planned: 18/03/2020

Actual: 17/03/2020

Date of interim report, if expected

Planned: 01/03/2018

Date of final study report

Planned: 17/03/2021

Actual: 15/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20150262_01.02.06 Public Redacted Protocol Ver 1.0 English.pdf (1.9 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

20150262

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe carfilzomib utilisation in routine clinical practice, including dosage, administration schedule, regimen, duration of treatment, and reason for discontinuation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

KYPROLIS

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Adult patients with multiple myeloma who had received at least 1 prior therapy prior to receiving carfilzomib in routine clinical practice and who had received at least 1 administration of carfilzomib as prescribed by their physician were considered for enrolment into the study.

Inclusion criteria:

1. age 18 years or older at the time of carfilzomib initiation

2. at least 1 prior line of MM treatment has been received
3. Carfilzomib treatment has been initiated per routine practice and is currently ongoing
4. At least 1 administration of carfilzomib in a combination regimen has been received
5. Provided written informed consent prior to abstraction of any data, in countries where written infomred consent is required

Exclusion criteria:
1. Subjects who are receiving carfilzomib treatment within a compassionate use program will not be eligible to take part in this observational study

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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)

Special population of interest

Other

Special population of interest, other

Multiple myeloma patients

Estimated number of subjects

651

Study design details

Outcomes

Carfilzomib dose, regimen, dosing frequency, administration schedule, and duration of treatment Carfilzomib dose and frequency changes, interruptions, or delays Reasons for discontinuation of carfilzomib treatment Changes in dose and frequency of concomitant MM therapies given as part of the carfilzomib regimen, Demographic and MM characteristics Treatment history Carfilzomib safety profile Response to treatment Type of relapse ECOG performance status category at MM diagnosis and carfilzomib initiation Unplanned hospitalisations Reason for choosing treatment, dose, regimenConcomitant therapy Cardiovascular assessment per routine practice at carfilzomib initiation and cardiac adverse events

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Data analysis plan

The approach to the statistical analysis will be generally descriptive, no formal hypotheses will be tested. Categorical data will be summarised by the number and percentage of subjects in each category. Two-sided 95% CIs will be presented, calculated using Wilson’s method where appropriate. Continuous data will be summarised by mean, SD, median, lower and upper quartiles, and minimum and maximum values. Time-to-event endpoints (DOR and time to progression) will be summarised using Kaplan-Meier methodology. Analyses will be presented overall and by country/region.

Documents

Study results

Abstract of 20150262 Carfilzomib Observational Research Study Report Published Report.pdf (177.26 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Chart review

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