Comprehensive Analysis of Clinical Parameters That May Inform the Choice of Dose Regimen for Carfilzomib 20/27mg/m2 or 20/56mg/m2 With and Without Dexamethasone (20200381)

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Study Finalised

Administrative details

EU PAS number

EUPAS37838

Study ID

46723

DARWIN EU® study

No

Study countries

- ☐ Australia
- ☐ Austria

- [ ] Belgium
- [ ] Brazil
- [ ] Bulgaria
- [ ] Canada
- [ ] China
- [ ] Czechia
- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Israel
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Netherlands
- [ ] New Zealand
- [ ] Norway
- [ ] Poland
- [ ] Romania
- [ ] Russian Federation
- [ ] Serbia
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Taiwan
- [ ] Thailand
- [ ] Türkiye
- [ ] Ukraine
- [ ] United Kingdom

United States

Study description

The aim of this study is to pool data from 13 Amgen-sponsored clinical trials to describe the benefit-risk profile of each carfilzomib (K) regimen based on the clinical parameters associated with efficacy and safety outcomes of subjects treated with one of four different dosing regimens to inform the choice of carfilzomib regimen. The dosing regimens of carfilzomib include a therapeutic dose of 27mg/m2 or 56mg/m2, each as monotherapy or in combination with dexamethasone (K27, K56, Kd27, Kd56). The study population is 1817 subjects with relapsed or refractory multiple myeloma (RRMM), aged 18 and above, who received consistent twice-weekly K treatment with K27, Kd27, K56, or Kd56 via an Amgen-sponsored clinical trial.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

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: 01/10/2020

Actual: 01/10/2020

Study start date

Planned: 01/02/2022

Actual: 15/12/2021

Data analysis start date

Planned: 31/03/2022

Actual: 01/04/2022

Date of final study report

Planned: 31/01/2023

Actual: 31/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

EUPAS37838-38139.pdf (1.27 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

Protocol-20200381

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Identify clinical parameters that may inform choice of carfilzomib dose regimen.

Data collection methods:

Secondary use of data

Main study objective:

Describe the benefit-risk profile for each pre-specified K regimen (K27, Kd27, K56, Kd56) based on the clinical parameters that are associated with efficacy and safety outcomes from the pooled data meeting the criteria for sample size and completeness of covariates.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, post-hoc, pooled analysis

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Additional medical condition(s)

Relapsed or refractory multiple myeloma (RRMM)

Population studied

Short description of the study population

Patients with refractory relapsed multiple myeloma (RRMM) who received consistent twice-weekly K treatment with K27, Kd27, K56, or Kd56 identified from the Amgen-sponsored clinical trial between 2005 and 2019.

Inclusion Criteria:

Step 1: Identify all Amgen acquired or sponsored studies in Onyx-owned or RAVE database until 14 July 2019.

Step 2: Within those databases, identify all clinical studies that enrolled subjects with RRMM

· These subjects may have received any number of prior lines of therapy

Step 3: Among those clinical studies, identify all subjects treated with K dosing frequency of twice a week at the start of each week for three of the four-week cycles (days 1, 2, 8, 9, 15, 16 for each 28-day cycle) for all cycles of treatment.

Step 4: Separate these subjects based on treatment of K27, Kd27, K56, or Kd56.

If the regimen in the individual clinical trial dictates that the first and/or second cycle of K therapy is 15mg/m2 or 20mg/m2, but 27mg/m2 is specified for subsequent K cycles of therapy, then the clinical trial will be included for subjects who receive K at 27mg/m2 with or without dexamethasone.

· If the regimen in the clinical trial dictates that the first cycle of K therapy is 27mg/m2, but 56mg/m2 is specified for subsequent K cycles of therapy, then

the
clinical trial will be included for subjects who receive K at 56 mg/m2 with or without dexamethasone.
· Therapeutic dexamethasone dosing will be based on the subject receiving at least 20mg per week.

Exclusion Criteria:
Exclude any subjects duplicated among the different carfilzomib regimens.

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

Renal impaired

Hepatic impaired

Immunocompromised

Other

Special population of interest, other

Multiple Myeloma patients

Estimated number of subjects

1817

Study design details

Outcomes

•Progression free Survival (PFS) •Objective Response •Grade 3 or higher adverse events and Serious Adverse Events (SAE) for the following key risks that may impact the overall benefit risk profile of carfilzomib: oCardiac failure (SMQN) oAcute Renal failure (SMQN) oHypertension (SMQN) oCardiac events •Fatal adverse events, Compare the same efficacy and safety outcomes as the primary outcome for K dosing regimens with dexamethasone (Kd27 versus Kd56).

Data analysis plan

Data from the 13 clinical trials will be pooled for the analysis of clinical parameters that may inform the choice of K dose regimen. All analyses will be descriptive. No formal hypothesis testing is planned for the efficacy and safety comparison between carfilzomib dosing regimens.

Documents

Study results

20200381 Observational Research Study Report Abstract.pdf (110.2 KB)

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

Data sources (types), other

Retrospective, post-hoc, pooled analysis of interventional, Amgen-sponsored carfilzomib studies.

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