An Observational Study to Estimate
Incidence Rates of Heart Failure Among US
Racial and Ethnic Minority Patients With
Multiple Myeloma Treated or Not Treated
With Carfilzomib

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# Administrative details

EU PAS number
EUPAS30748
Study ID
38535
DARWIN EU® study
No
Study countries  United States

#### Study description

On 14 June 2018, Amgen submitted to the FDA a labeling supplement which proposed an update to the Kyprolis US Prescribing Information indicating that the risk of developing cardiac failure is higher among Asian patients. This increased risk was identified following analysis of data from Amgen sponsored clinical trials and postmarketing reports. On 14 December 2018, the FDA issued a complete response letter, which highlighted the lack of evidence to support that there is an increased risk of cardiac failure in US Asian patients. In addition, based on the submission of this supplement, the Agency stated the concern of the potential differential risk of cardiac failure among racial and ethnic minorities. To address these issues, Amgen agreed to conduct a postmarketing requirement in the form of an observational study to estimate incidence rates of heart failure among US racial and ethnic minority patients with multiple myeloma treated or not treated with carfilzomib.

#### **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**

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: 01/08/2019

Actual: 15/02/2019

## Study start date

Planned: 01/09/2019

Actual: 01/09/2019

## Data analysis start date

Planned: 01/10/2019

Actual: 01/10/2019

## **Date of final study report**

Planned: 30/06/2020

Actual: 17/08/2020

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Amgen

# Study protocol

20190012\_Public Redacted Protocol Amend 1 English.pdf (846.34 KB)

# Regulatory

Was the study required by a regulatory body?

Yes

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:

Assessment of risk minimisation measure implementation or effectiveness

#### **Data collection methods:**

Secondary use of data

#### Main study objective:

1. Estimate the incidence rates of cardiac failure in US racial and ethnic populations of patients with multiple myeloma treated with carfilzomib2. Estimate the incidence rates of cardiac failure in US racial and ethnic populations of patients with multiple myeloma not treated with carfilzomib

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Name of medicine

**KYPROLIS** 

#### Medical condition to be studied

Plasma cell myeloma

# Population studied

#### Short description of the study population

Patients who satisfied the following key criteria were eligible:

- 1. Multiple myeloma diagnosis, as determined utilizing an algorithm based upon presence of a combination of ICD-9-CM and ICD-10-CM diagnosis codes, Current Procedural Terminology codes for diagnosis tests or National Drug Codes and Healthcare Common Procedure Coding System codes for treatments
- 2. Age  $\geq$  18 years.
- 3. Receipt of carfilzomib or other multiple myeloma treatments in at least 1 LOT
- 4. Continuously enrolled in medical and pharmacy insurance coverage for 12 months before the treatment index.

#### **Exclusion Criteria**

Patients with missing or unknown race/ethnicity variable or evidence of renal transplant or dialysis were excluded.

#### **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**

3689

# Study design details

#### **Outcomes**

The primary outcome is the incidence rate of heart failure in the US white, black, Asian, and Hispanic multiple myeloma patients treated with carfilzomib-containing or carfilzomib-free drug regimens.

#### Data analysis plan

The incidence rate of heart failure will be estimated for US racial and ethnic minority multiple myeloma patients treated with carfilzomib-containing or carfilzomib-free regimens. As exploratory analysis, risk for heart failure will be compared between myeloma patients treated with carfilzomib-containing vs. carfilzomib-free regimens among whites and blacks in the US.

## **Documents**

#### Study results

20190012\_ Observational Research Study Report Published Report.pdf (9.41 MB)

# 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)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

# 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