

# An observational study of Cardiovascular complications of Carfilzomib treatment in clinical practice (Cardiovascular complications of carfilzomib)

**First published:** 10/05/2017

**Last updated:** 30/01/2020

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS19053

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### Study ID

33299

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### DARWIN EU® study

No

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### Study countries

Greece

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## **Study description**

This is an, observational, non interventional, study in patients with relapsed or refractory myeloma treated with carfilzomib (CFZ), according to the approved indications. Patients will be evaluated prospectively for different parameters of vascular function, blood pressure and cardiac function in conjunction with studies of proteasome inhibition and function. The aim of this study is to provide insights into the effects of carfilzomib on vascular function and the mechanisms of UPS inhibition on cardiovascular complications of proteasome inhibitors. Primary objective is to describe cardiovascular complications associated with the use of carfilzomib and investigate the role of the UPS inhibition, in patients treated with carfilzomib and dexametahsone, on atheromatosis and vascular inflammation and function. Secondary objective is to outline the clinical significance of carfilzomib toxicity in hemodynamic parameters and cardiovascular function and vascular structure. Primary end points are • Changes in hemodynamic markers (peripheral and aortic office blood pressure and 24 hour ambulatory BP monitoring parameters) and in peripheral vascular function (endothelial function, arterial stiffness, arterial wave reflections) before, during and after study drug administration Secondary endpoints are • Changes in subclinical atherosclerosis markers (carotid intima-media thickness and vascular wall and plaque echogenicity) • changes in markers of cardiac function (ejection fraction, systolic and diastolic strain and strain rate) • changes in circulating cardiac and vascular inflammatory biomarkers before and after study drug administration Patients with relapsed or refractory myeloma treated with carfilzomib as per approved indications will be enrolled in the study

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## **Study status**

Ongoing

## **Research institutions and networks**

## Institutions

National and Kapodistrian University of Athens

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Institution

Department of Clinical Therapeutics

## Contact details

### Study institution contact

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Study contact

[stamatelopoulosk@yahoo.gr](mailto:stamatelopoulosk@yahoo.gr)

### Primary lead investigator

EFSTATHIOS KASTRITIS

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/06/2017

Actual: 01/06/2017

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### **Study start date**

Planned: 03/07/2017

Actual: 03/07/2017

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### **Data analysis start date**

Planned: 03/07/2019

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### **Date of final study report**

Planned: 01/06/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AMGEN

## Study protocol

[Protocol \\_ CFZ Vacsulature\\_revised\\_safety changes new version-2.pdf\(616.89 KB\)](#)

## Regulatory

### **Was the study required by a regulatory body?**

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Other

#### **If 'other', further details on the scope of the study**

Cardiovascular indices

#### **Main study objective:**

- to describe cardiovascular complications associated with the use of carfilzomib and investigate the role of the UPS inhibition, in patients treated with carfilzomib and dexamethasone, on atheromatosis and vascular inflammation and function

## Study Design

## **Non-interventional study design**

Other

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## **Non-interventional study design, other**

Intensive monitoring schemes, prescription event monitoring

# Study drug and medical condition

## **Name of medicine**

KYPROLIS

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## **Medical condition to be studied**

Plasma cell myeloma recurrent

# Population studied

## **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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## **Estimated number of subjects**

46

# Study design details

## **Outcomes**

Changes in hemodynamic markers (peripheral and aortic office blood pressure and 24 hour ambulatory BP monitoring parameters) and in peripheral vascular function (endothelial function, arterial stiffness, arterial wave reflections) before, during and after study drug administration, • Changes in subclinical atherosclerosis markers (carotid intima-media thickness and vascular wall and plaque echogenicity) • changes in markers of cardiac function (ejection fraction, systolic and diastolic strain and strain rate) • changes in circulating cardiac and vascular inflammatory biomarkers before and after study drug administration

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## **Data analysis plan**

Data will be presented as mean  $\pm$  standard deviation (SD). Continuous variables will be tested for normal distribution with the Kolmogorov-Smirnov test. Repeated measures ANOVA will be performed in order to assess significant variations of parameters of interest over time. Linear mixed models analysis will be performed in order to adjust for possible confounders over time. All tests will be two-tailed and statistical significance will be considered for P values less than 0.05. All statistical analyses will be performed using SPSS version 21 for windows (Chicago, ILL, USA).

# Data management

## Data sources

### **Data sources (types)**

[Other](#)

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### **Data sources (types), other**

Prospective patient-based data collection, Prescription event monitoring, Patients will be evaluated prospectively for different parameters of vascular function, blood pressure and cardiac function in conjunction with studies of proteasome inhibition and function.

## 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