

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

Study ID

33299

DARWIN EU® study

No

Study countries

 Greece

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 dexamethasone, 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

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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Primary lead investigator

EFSTATHIOS KASTRITIS

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2017

Actual: 01/06/2017

Study start date

Planned: 03/07/2017

Actual: 03/07/2017

Data analysis start date

Planned: 03/07/2019

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

Non-interventional study design, other

Intensive monitoring schemes, prescription event monitoring

Study drug and medical condition

Medicinal product name

KYPROLIS

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)
-

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

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

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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No