Disease progression and resource utilization in treated relapse/refractory multiple myeloma in Spain (PREMIERE)

First published: 18/08/2015

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10691

Study ID

21438

DARWIN EU® study

No

Study countries

☐ Spain

Study description

This is a retrospective chart review study to explore progression-free survival (PFS), overall survival (OS), health resource utilisation (HRU) and their associated costs in a sample of patients treated for a first episode of RRMM in a real-world setting in Spain. While data on treatments and resources will be collected from patients' clinical notes, costs will be extracted from a local cost databases. Such information will be used to populate a cost-effectiveness model for Spain using real world data.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company** **ENCePP partner**

Multiple centres: 27 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/10/2014

Study start date

Planned: 07/09/2015

Actual: 11/09/2015

Data analysis start date

Planned: 01/09/2015

Actual: 14/12/2015

Date of interim report, if expected

Actual: 30/12/2015

Date of final study report

Planned: 31/10/2016

Actual: 23/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BMS, Bristol Myers Squibb

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 topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

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

Treatment patterns and resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to estimate progression free survival (PFS) in a cohort of patients in Spain treated for a first episode of relapse/refractory multiple myeloma (RRMM).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective chart review

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Patients treated for a first episode of relapse/refractory multiple myeloma in in a real-world setting in Spain.

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

375

Study design details

Outcomes

Progression-free survival (PFS), Overall survival (OS), socio-demographic, clinical and treatment characteristics, healthcare resource utilisation and associated costs, and reasons for change in Line of Therapy (LOT)

Data analysis plan

PFS and OS will be described using Kaplan-Meier plots with estimation of the median PFS and 95% CIs. The number of events and the number of patients at risk by 1 month periods will be reported. If the median level (50%) is not reached, cumulative incidence by 3 month periods will be provided. Analyses will be performed overall and stratified by age, presence of previous treatment with immunomodulatory drugs and prior LOT (1st, ≥ 2). Patient characteristics at the index date will be summarized. Descriptive statistics will be used to describe treatment characteristics by LOT during follow-up. Summary descriptive statistics will report HRU and costs during the follow-up in the pre-/post-progression states. The overall proportion of RRMM patients who undergo a change in LOT during follow-up, proportions by LOT and reasons for change will be presented. To identify patient- and center-level characteristics associated with PFS Cox regression models will be used.

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 source(s), other

eSalud Spain

Data sources (types)

Other

Data sources (types), other

Patient´s clinical records

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

Unknown