An Observational Cohort Study on Multiple Myeloma Patients in Finland

First published: 01/09/2017

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19582

Study ID

47393

DARWIN EU® study

No

Study countries

☐ Finland

Study description

Multiple myeloma (MM) is a progressive clonal haematologic malignancy of plasma cells. In Finland, approximately 400 new MM cases are diagnosed each year, primarily amongst the elderly. The average survival time following

diagnosis is 5-6 years, but prognosis varies greatly and the recent introduction of novel therapies has improved overall survival. However, in Finland, it is not completely known how MM patients are treated in real-life clinical settings. Also, the prevalence of various risk factors, and the effect of a patient's risk status on treatment, e.g. on type, duration, and outcomes such as overall survival and time to next treatment, have not been sufficiently reported. To evaluate the effectiveness of new MM treatments in real-life clinical practice it may not be possible to find suitable comparators shortly after a new treatment has entered the market. To better understand treatment and outcomes of MM in Finland, Takeda Finland will conduct a descriptive retrospective study using nationwide data from the Finnish Hematology Register (FHR). The "whole study cohort" will include patients diagnosed for MM at age 18 years or older during 1 Jan 2010 – 31 Dec 2015. The "actual study cohort" will include a subset of the above patients who are treated for MM during 1 Jan 2010 – 31 Dec 2016, and who have at least one year of potential follow-up time following start of treatment (to 31 Dec 2017). Characteristics of all MM patients recorded in the FHR will be described on an overall level. This study aims to provide a representative description of MM patient characteristics, treatment and outcomes in Finland. The results can then be used as a historical reference for evaluating the changing MM treatment landscape. This study also aims to identify subgroups of patients who may not be able to receive or must discontinue/modify certain conventional therapies due to their unsuitable nature, and to evaluate the outcomes under current and past treatment options.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Katja Hakkarainen PAS_registrations@iqvia.com

Study contact

PAS_registrations@iqvia.com

Primary lead investigator

Massoud Toussi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/12/2016

Actual: 03/12/2016

Study start date

Planned: 03/09/2018

Actual: 12/09/2017

Data analysis start date
Planned: 02/10/2017

Actual: 21/09/2018

Date of final study report
Planned: 28/02/2019

Actual: 29/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

ER-9542 Takeda Multiple Myeloma FIN Protocol_v1.0_2017-08-08_signed.pdf
(1.62 MB)

ER-9542 Takeda Multiple Myeloma FIN Protocol_v2.0_CLEAN_signatures.pdf
(876.57 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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objectives of the study are to describe the demographics, disease characteristics, and treatment patterns of Finnish MM patients, to identify patient, disease, and treatment-related factors associated with study outcomes, and to identify subpopulations of Finnish MM patients.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective observational study

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

The study will include:
1) Patients diagnosed with MM during the period 01 January 2010 – 31 December 2015 and aged 18 years or older at diagnosis (i.e. the whole study cohort).
2) Patients diagnosed with MM during the period 01 January 2010 – 31 December 2015 and treated for MM during the period 01 January 2010 – 31 December 2016 and aged 18 years or older at diagnosis. This actual study cohort will include only patients for whom at least one treatment initiation date can be identified and
who have a minimum of one year of potential follow-up time (to 31 December 2017).

Inclusion criteria

• MM diagnosis recorded in the FHR
• Age 18 years or older at the time of MM diagnosis

Exclusion criteria
• Multiple haematological diagnoses in the FHR for which the treatments cannot be differentiated

---

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

1600

Study design details

Outcomes

The primary outcomes are patient demographics, disease characteristics, and treatment patterns e.g. types of treatments and treatment lines. The secondary outcomes are patient, disease, and treatment-related factors associated with

treatment selection, overall survival, treatment duration, and time to next treatment.

Data analysis plan

Patient demographics and disease characteristics will be described for the whole study cohort by mean, standard deviation, median, 25th and 75th percentiles, minimum and maximum (continuous variables) and by proportion and frequency per category (categorical variables). Study outcomes will be described with the Kaplan-Meier estimator in the actual study cohort and in identified subpopulations, and stratified by demographics, disease characteristics, and types and lines of treatment. Factors associated with study outcomes will be identified using a multivariate Cox regression model, with additional demographic variables, disease characteristics and treatment patterns added as variables of interest. Factors associated with treatment selection will be identified using a multivariate logistic model. Sensitivity analyses will be performed to test robustness of the models based on representativeness of the actual study cohort, treatment line definitions, and missingness of certain variables.

Documents

Study results

ER-9542 Takeda MM FIN_Study report v1.0_20200529_final.pdf(1.34 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)

Disease registry

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