Prevalence of multiple myeloma

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Administrative details

PURI

https://redirect.ema.europa.eu/resource/104329

EU PAS number

EUPAS104328

Study ID

104329

DARWIN EU® study

No

Study countries

France

Germany

United Kingdom

Study description

A descriptive study to determine the complete prevalence of Multiple Myeloma in electronic health records of three European countries

Study status

Finalised

Research institution and networks

Institutions

European Medicines Agency (EMA) First published: 01/02/2024

Last updated 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luis Pinheiro

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned:

03/02/2022

Actual:

03/02/2022

Study start date

Planned:

03/02/2022

Actual:

03/02/2022

Date of final study report

Planned:

15/03/2022

Actual:

13/05/2022

Sources of funding

Study protocol

Data analysis plan - Multiple Myeloma - 20220224 - v1_For Publication_CLEAN.pdf(141.82 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)? Not applicable

Methodological aspects

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary data collection

Main study objective:

to determine the complete prevalence of Multiple Myeloma in electronic health records of three European countries (France, Germany, United Kingdom).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

The study included patients with at least one encounter (consultation, prescription) to determine the prevalence of multiple myeloma, between 2015 and 2020, identified from the IMRD databases.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

10000

Study design details

Data analysis plan

Prevalence was determined using the any-time method. The denominator was calculated as the count of patients of all ages who are eligible, i.e. had at least one observation (consultation or prescription), during the period of interest. The numerator was computed

as the count of patients that had at least one code for Multiple Myeloma, per a list of preselected codes, during the period starting from the start of data collection for the patient to the end of the period of interest (i.e. complete prevalence). Results were not stratified by age or gender.

Documents

Study results

Multiple Myeloma Prevalence Report - 20220513 - To be published_CLEAN.pdf(361.29 KB)

Data management

Data sources

Data source(s)

Disease Analyzer Germany Disease Analyzer - OMOP

Data sources (types)

Drug dispensing/prescription data 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