DARWIN EU® Multiple myeloma: patient characterisation, treatments and survival in the period 2012-2022

First published: 04/07/2023

Last updated: 25/09/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106363

EU PAS number

EUPAS105033

Study ID

106363

DARWIN EU® study

Yes

Study countries

☐ Estonia

- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Spain

Study description

The overall objective of this study is to characterise patients with multiple myeloma diagnosed in the period 2012-2022. The specific objectives of this study are:

1. To describe demographic and clinical characteristics of patients with multiple myeloma at the time of diagnosis.
2. To describe multiple myeloma treatments (including combinations and regimen types, e.g. induction, maintenance, etc.).
3. To describe multiple myeloma treatment sequences.
4. To estimate the overall survival of incident multiple myeloma cases during the study period (2012-2022).

Study status

Finalised

Research institutions and networks

Institutions

IQVIA NL, Real-World-Evidence

- [ ] Netherlands

First published: 25/11/2022

Last updated: 21/03/2025

Institution | Other | ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Clinical Data Science (IKNL), Netherlands Comprehensive Cancer Organisation

Netherlands

First published: 04/04/2023

Last updated: 04/04/2023

Institution | Not-for-profit | ENCePP partner

Parc de Salut Mar Barcelona (PSMAR)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Hospital District of Southwest Finland (HSDF)

Finland

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Bordeaux University Hospital (CHU de Bordeaux)

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

University of Tartu

Estonia

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- [ ] Belgium
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Hungary
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Spain
- [ ] United Kingdom

First published: 01/02/2024

Last updated: 11/06/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Talita Duarte-Salles

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/03/2023

Actual: 07/03/2023

Study start date

Planned: 01/01/2012

Actual: 01/01/2012

Date of final study report

Planned: 01/11/2023

Actual: 13/11/2023

Sources of funding

- EMA

Study protocol

D2.2.3_Darwin_EU_Study_Protocol_P2 C1-001_v3.0_Final.pdf(684.53 KB)

DARWIN EU Final Study Protocol P2 C1-001 Multiple myeloma.pdf(1.46 MB)

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

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To characterise patients with multiple myeloma(MM) diagnosed 2012-2022. Specific objectives are to describe demographic and clinical characteristics of patients with MM at the time of diagnosis, MM treatments and MM treatment sequences and to estimate survival of incident MM cases during the study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Etidronate (ATC code: M05BA01), Etidronate (ATC code: L01XH03)

Study drug International non-proprietary name (INN) or common name

AXICABTAGENE CILOLEUCEL

BORTEZOMIB

BREXUCABTAGENE AUTOLEUCEL

CARFILZOMIB

CISPLATIN

CYCLOPHOSPHAMIDE

DARATUMUMAB

DENOSUMAB

DEXAMETHASONE

ELOTUZUMAB

IDECABTAGENE VICLEUCEL

ISATUXIMAB

LENALIDOMIDE

LISOCABTAGENE MARALEUCEL

POMALIDOMIDE

SELINEXOR

THALIDOMIDE

TISAGENLECLEUCEL

VENETOCLAX

Anatomical Therapeutic Chemical (ATC) code

(H02AB02) dexamethasone

dexamethasone

(H02AB07) prednisone

prednisone

(L01AA01) cyclophosphamide

cyclophosphamide

(L01AA03) melphalan

melphalan

(L01AA09) bendamustine

bendamustine

(L01CA02) vincristine

vincristine

(L01CB01) etoposide

etoposide

(L01DB01) doxorubicin

doxorubicin

(L01XA01) cisplatin

cisplatin

(L01XC23) elotuzumab

elotuzumab

(L01XC24) daratumumab

daratumumab

(L01XC38) isatuximab

isatuximab

(L01XG02) carfilzomib

carfilzomib

(L01XG03) ixazomib

ixazomib

(L01XL06) brexucabtagene autoleucel

brexucabtagene autoleucel

(L01XL07) idecabtagene vicleucel

idecabtagene vicleucel

(L01XL08) lisocabtagene maraleucel

lisocabtagene maraleucel

(L01XX32) bortezomib

bortezomib

(L01XX52) venetoclax

venetoclax

(L01XX66) selinexor

selinexor

(L01XX70) axicabtagene ciloleucel

axicabtagene ciloleucel

(L01XX71) tisagenlecleucel

tisagenlecleucel

(L04AX02) thalidomide

thalidomide

(L04AX04) lenalidomide

lenalidomide

(L04AX06) pomalidomide

pomalidomide

(M05BA02) clodronic acid

clodronic acid

(M05BA03) pamidronic acid

pamidronic acid

(M05BA06) ibandronic acid

ibandronic acid

(M05BA08) zoledronic acid

zoledronic acid

(M05BX04) denosumab

denosumab

Medical condition to be studied

Plasma cell myeloma

Plasmacytoma

Additional medical condition(s)

Amyloid light chain amyloidosis due to multiple myeloma, Asymptomatic multiple myeloma, Bone marrow: myeloma cells, Extramedullary plasmacytoma, Hypogammaglobulinemia due to multiple myeloma, IgA myeloma, IgD myeloma, IgG myeloma, Indolent multiple myeloma, Kappa light chain myeloma, Lambda light chain myeloma, Light chain myeloma, Light chain nephropathy due to multiple myeloma, Multiple myeloma, Multiple myeloma in remission, Multiple solitary plasmacytomas, Myeloma-associated amyloidosis, Myeloma kidney, Neuropathy due to multiple myeloma, Non-secretory myeloma, Osteoporosis co-occurrent and due to multiple myeloma, Osteosclerotic myeloma, Plasma cell leukemia, Plasma cell leukemia in relapse, Plasma cell leukemia in remission, Primary cutaneous plasmacytoma, Relapse multiple myeloma, Smoldering myeloma, Solitary osseous myeloma

Population studied

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)

Estimated number of subjects

20000000

Study design details

Outcomes

Treatment/s initiated at index date, 1 to 30, 1 to 90 and/or 1 to 365 days post index date, and death.

Data analysis plan

Large-scale patient-level characterisation will be conducted. Age and sex at time of multiple myeloma diagnosis, medical history and medication use will be described. The number and % of patients receiving each of a pre-specified list of multiple myeloma treatments and treatment combinations will also be described. Additionally, treatment patterns and sequences over time will be described. Survival will be estimated as the probability of survival from any cause of death and will be reported using Kaplan-Meier plots. This analysis will be conducted only for databases with complete information on mortality. A minimum cell count of 5 will be used when reporting results, with any smaller counts obscured.

Documents

Study results

DARWIN_EU_D2.2.4_Study Report_P2-C1-001_Multiple_Myeloma_v3.0.pdf(4.08 MB)

Study, other information

Study Protocol P2 C1-001 Version 3.1 final.pdf(1.49 MB)

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

Institut Municipal d'Assistència Sanitària Information System

Estonian Biobank

Auria Clinical Informatics (FinOMOP)

Clinical Data Warehouse of the Bordeaux University Hospital

Netherlands Cancer Registry

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Hospital data and biobank data

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No