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

First published: 04/07/2023
Last updated: 13/05/2024

Study | Finalised

Administrative details

Contact details

Study institution contact
Ilse Schuemie
Study contact

study@darwin-eu.org
Primary lead investigator
Talita Duarte-Salles
Primary lead investigator

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 institution and networks

Institutions

IQVIA
United Kingdom
First published: 12/11/2021
Last updated 22/04/2024

Institution | Non-Pharmaceutical company | 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 16/04/2024

Network

Study timelines

Date when funding contract was signed

Planned:
07/03/2023
Actual:
07/03/2023

Data collection
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

ZOLEDRONIC ACID

Anatomical Therapeutic Chemical (ATC) code
100000096036
dexamethasone
100000096041
prednisone
100000096617
cyclophosphamide
100000096619
melphalan
100000116251
bendamustine
100000096674
vincristine
100000096678
etoposide
100000096692
doxorubicin
100000096708
cisplatin
100000170636
elotuzumab
200000003285
daratumumab
200000012517
isatuximab
200000016136
carfilzomib
200000016137
ixazomib
200000028541
brexucabtagene autoleucel
200000030589
idecabtagene vicleucel
200000041609
lisocabtagene maraleucel
100000096761
bortezomib
100000173048
venetoclax
200000012111
selinexor
200000016155
axicabtagene ciloleucel
200000016156

tisagenlecleucel
100000096883
thalidomide
100000096885
lenalidomide
100000157885
pomalidomide
100000097109
clodronic acid
100000097110
pamidronic acid
100000097113
ibandronic acid
100000097115
zoledronic acid
100000116261
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

Results tables
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
Disease Analyzer Germany
Institut Municipal d'Assistència Sanitària Information System
Estonian Biobank
Auria Clinical Informatics
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

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No