DARWIN EU® Natural history of dermatomyositis (DM) and polymyositis (PM) in adults and paediatric populations

First published: 13/11/2023

Last updated: 25/09/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/107455

EU PAS number

EUPAS107454

Study ID

107455

DARWIN EU® study

Yes

Study countries

☐ Estonia

- [ ] France
- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

The overall objective of this study is to describe and characterise dermatomyositis (DM), polymyositis (PM) and their juvenile forms (JDM and JPM), in terms of prevalence, natural history of the disease, disease severity, and treatment. The specific objectives of this study are to estimate the yearly prevalence of DM and PM in adult and paediatric populations, overall and by sex, to characterise patients and describe age at disease onset for DM, PM, JDM and JPM, to describe the occurrence in adults and children of biomarker measurements and clinical manifestations and to describe disease severity including organ involvement before, at the time, and after a diagnosis of DM, PM, JDM and JPM. Additionally, the objective of the study is to describe treatment administered after a diagnosis of DM, PM, JDM and JPM.

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

University of Bordeaux

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

University of Oxford, United Kingdom

Networks

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

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

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

Ilse Schuemie

Study contact

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Primary lead investigator

Albert Prats Uribe

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/07/2023

Actual: 26/07/2023

Study start date

Planned: 01/01/2006

Actual: 01/01/2006

Date of final study report

Planned: 30/11/2023

Actual: 21/11/2023

Sources of funding

- EMA

Study protocol

DARWIN EU Final Study Protocol P2 C1-007 DM and PM.pdf(1.71 MB)

Darwin_EU_Study_Protocol_P2-C1-007_v1.1final.pdf(1.67 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:

The overall objective of this study is to describe and characterise dermatomyositis (DM), polymyositis (PM) and their juvenile forms (JDM and JPM), in terms of prevalence, natural history of the disease, disease severity, and treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

- Prednisone
- Cyclosporine (ATC code: L04AD01)
- Beta interferone -1a
- Beta interferone-1b
- Inmunoglobulines
- Brimionidine

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

ABATACEPT

ADALIMUMAB

AZATHIOPRINE

BASILIXIMAB

CHLOROQUINE

CYCLOPHOSPHAMIDE

ECULIZUMAB

ETANERCEPT

HYDROXYCHLOROQUINE

INFLIXIMAB

METHOTREXATE

METHYLPREDNISOLONE

MYCOPHENOLATE MOFETIL

RITUXIMAB

Anatomical Therapeutic Chemical (ATC) code

(A07EA03) prednisone

prednisone

(H02AB04) methylprednisolone

methylprednisolone

(J06BA) Immunoglobulins, normal human

Immunoglobulins, normal human

(L01AA01) cyclophosphamide

cyclophosphamide

(L01FA01) rituximab

rituximab

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b

(L04AA06) mycophenolic acid

mycophenolic acid

(L04AA24) abatacept

abatacept

(L04AA25) eculizumab

eculizumab

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AB04) adalimumab

adalimumab

(L04AC02) basiliximab

basiliximab

(L04AD02) tacrolimus

tacrolimus

(L04AX01) azathioprine

azathioprine

(L04AX03) methotrexate

methotrexate

(P01BA01) chloroquine

chloroquine

(P01BA02) hydroxychloroquine

hydroxychloroquine

(S01EA05) brimonidine

brimonidine

Medical condition to be studied

Dermatomyositis

Polymyositis

Juvenile polymyositis

Additional medical condition(s)

Juvenile dermatomyositis, Neonatal dermatomyositis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

19500000

Study design details

Data analysis plan

Point prevalence of each outcome of interest (DM, PM, JDM, JPM), with every individual deemed to have the diagnosis from first occurrence until end of follow-up calculated on an annual basis as of the 1st January for each year, estimated overall and stratified by age and sex. Age and sex at time of DM, PM, JDM, JPM diagnosis (index date) will be described for each of the generated study cohorts (Objective 2). Large-scale patient-level characterisation will be conducted for objectives 3 to 5. Occurrence of co-morbidities, measurements, clinical manifestations, and severity markers will be assessed for anytime –and up to 365 days before index date, for 364 to 91, for 90 to 31, and for 30 to 1 day before index date, and at index date. We will also report them for 1 to 90, 91 to 180, 181 to 365 days, 366 to 1095, 1096 to 1825 days, and 1826 days to any time post index date.

Documents

Study results

DARWIN EU Final Study Report C1-007 DM and PM.pdf(5.48 MB)

Data management

Data sources

Data source(s)

The Information System for Research in Primary Care (SIDIAP)

IQVIA Disease Analyzer Germany

Clinical Data Warehouse of the Bordeaux University Hospital

Clinical Practice Research Datalink (CPRD) GOLD

Estonian Biobank

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Secondary care, Outpatient specialist setting, Hospital care

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