

# 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

### EU PAS number

EUPAS107454

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### Study ID

107455

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### DARWIN EU® study

Yes

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### Study countries

- ☐ Estonia
- ☐ France
- ☐ Germany
- ☐ Spain

☐ United Kingdom

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## 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.

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## 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:** 23/05/2025

**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@darwin-eu.org](mailto:study@darwin-eu.org)

**Study contact**

[study@darwin-eu.org](mailto:study@darwin-eu.org)

## 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

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### Study start date

Planned: 01/01/2006

Actual: 01/01/2006

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### 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

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## **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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

**Medicinal product name, 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

TACROLIMUS

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**Anatomical Therapeutic Chemical (ATC) code**

(A07EA03) prednisone

prednisone

(H02AB04) methylprednisolone

methyprednisolone

(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

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### **Medical condition to be studied**

Dermatomyositis

Polymyositis

Juvenile polymyositis

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### **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)

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### **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)

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## 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 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

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)  
[Other](#)

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### 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

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**CDM website**

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

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## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

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## Data characterisation

**Data characterisation conducted**

No