DARWIN EU® Treatment patterns of drugs used in adult and paediatric population with systemic lupus erythematosus

First published: 06/09/2023

Last updated: 30/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS106436

Study ID

106437

DARWIN EU® study

Yes

Study countries

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

Study description

Systemic SLE erythematosus: SLE is a multisystem autoimmune disorder of connective tissue characterized by autoantibodies that target nuclear antigens, remissions and flares, and a highly variable clinical presentation, disease course, and prognosis. The disease course is more severe in childhood-onset compared to adult-onset SLE, with higher prevalence of morbidity and lower survival rates. In contrast to adult SLE, there is limited good quality evidence on the treatment of childhood SLE. Therefore, to review new drug applications, it would be important for the European Medicines Agency EMA to understand the current clinical practice of treating SLE in paediatric population and differences with the treatment in adult population. The overall objective of this study is to characterise paediatric and adult patients with SLE diagnosed in the period 2013-2022. This will be a patient-level characterisation and drug utilisation study.

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

Parc de Salut Mar Barcelona (PSMAR)

Spain

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

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

☐ United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

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

Study contact

study@darwin-eu.org

Primary lead investigator

Daniel Prieto Alhambra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 06/07/2023

Actual: 06/07/2023

Study start date

Planned: 01/01/2013

Actual: 01/01/2013

Date of final study report

Planned: 31/10/2023

Actual: 01/12/2023

Sources of funding

- EMA

Study protocol

Study Protocol P2 C1-006 Version 2.1 final.pdf (1.93 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

Drug utilisation

Study design:

A retrospective cohort study of all patients newly diagnosed with SLE will be conducted. For the description of each treatment objective, a new drug user cohort will be used to characterise patient-level SLE drug utilisation.

Main study objective:

To characterise paediatric and adult patients with SLE.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

- Cyclosporine
- Fluocortolone
- Paramethasone
- Prednisone
- Triamcinolone
- Cortisone

- Prednylidene
- Rimexolone
- Deflazacort
- Cloprednol
- Meprednisone
- Cortivazol

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

AZATHIOPRINE

BELIMUMAB

BETAMETHASONE

CYCLOPHOSPHAMIDE

DEXAMETHASONE

HYDROCORTISONE

HYDROXYCHLOROQUINE

METHOTREXATE

METHYLPREDNISOLONE

MYCOPHENOLATE MOFETIL

PREDNISOLONE

RITUXIMAB

TACROLIMUS

VOCLOSPORIN

Anatomical Therapeutic Chemical (ATC) code

(H02AB01) betamethasone

betamethasone

(H02AB02) dexamethasone

dexamethasone

(H02AB03) fluocortolone

fluocortolone

(H02AB04) methylprednisolone

methylprednisolone

(H02AB05) paramethasone

paramethasone

(H02AB06) prednisolone

prednisolone

(H02AB07) prednisone

prednisone

(H02AB08) triamcinolone

triamcinolone

(H02AB09) hydrocortisone

hydrocortisone

(H02AB10) cortisone

cortisone

(H02AB11) prednylidene

prednylidene

(H02AB12) rimexolone

rimexolone

(H02AB13) deflazacort

deflazacort

(H02AB14) cloprednol

cloprednol

(H02AB15) meprednisone

meprednisone

(H02AB17) cortivazol

cortivazol

(L01AA01) cyclophosphamide

cyclophosphamide

(L01BA01) methotrexate

methotrexate

(L01FA01) rituximab

rituximab

(L04AA06) mycophenolic acid

mycophenolic acid

(L04AA26) belimumab

belimumab

(L04AD01) ciclosporin

ciclosporin

(L04AD02) tacrolimus

tacrolimus

(L04AD03) voclosporin

voclosporin

(L04AX01) azathioprine

azathioprine

(L04AX03) methotrexate

methotrexate

(P01BA02) hydroxychloroquine

hydroxychloroquine

Medical condition to be studied

Systemic lupus erythematosus

Population studied

Short description of the study population

The study population will include all individuals with a first diagnosis of SLE identified in the database during the patient selection period, which is between

01/01/2013 and 180 days prior to the end of available data in each database.

Age groups

- 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

19900000

Study design details

Data analysis plan

Large scale patient level characterisation will be conducted. Medical condition and medication use history will be reported at any time and 365 days prior to index date, respectively. The number and percentage of patients receiving each of a pre specified list of SLE treatments and treatment combinations will be described per calendar year. Additionally, sunburst plots and Sankey diagrams will be used to describe treatment patterns and sequences over time. For the new user cohort, the index date is the initiation of SLE treatment after SLE diagnosis. Treatment duration, initial dose strength, cumulative dose, number of prescriptions will be estimated for new users of each SLE treatments at the ingredient level. For all continuous variables, mean with standard deviation and median with interquartile range will be reported. For all categorical analyses,

number and percentages will be reported. A minimum cell count of 5 will be used when reporting results, smaller counts reported as 5.

Documents

Study report

DARWIN_EU_Study_Report_P2-C1-006_v2.0_final.pdf (2.83 MB)

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)

Institut Municipal d'Assistència Sanitària Information System / Hospital del Mar / PSMAR / (Hospital del Mar Information System)

IQVIA Disease Analyzer Germany

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Specialist care, Hospital linkage, Secondary 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