DARWIN EU® - Clinical characteristics and treatments used in adult and paediatric patients with systemic lupus erythematosus: a multinational European cohort study

First published: 04/11/2026

Last updated: 04/11/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000001164

Study ID

1000001164

DARWIN EU® study

Yes

Study countries

Croatia

Denmark

Spain

Sweden

United Kingdom

Study description

Systemic lupus erythematosus (SLE) is a chronic autoimmune disorder that can affect multiple organ systems, including the skin, joints, kidneys, nervous system, haematologic, and cardiovascular systems. It is characterised by autoantibodies targeting nuclear or phospholipid antigens, a relapsing disease course with remissions and flares, and a highly variable clinical presentation, disease course, and prognosis.

The estimated incidence of childhood-onset SLE is between 0.3 and 2.5 per 100,000 children. Although childhood-onset SLE shares many features with adult-onset SLE, including its pathogenesis and laboratory findings, it is generally associated with a more severe prognosis and different patterns of organ involvement. While treatment principles and drug classes used in childhood- and adult-onset SLE are similar, clinical management in children and adolescents must also account of the different licensed treatment in the two age groups.

Recent Real-World Evidence generated in the context of DARWIN EU®, and including data from four European countries, has shown that hydroxychloroquine and glucocorticoids remain the predominant first-line therapies in both adults and children, but paediatric patients are more likely to receive higher initial glucocorticoid doses compared to adults, highlighting the need for steroid-sparing strategies and for further research to inform paediatric SLE management.

Study status

Ongoing

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

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Last updated: 02/05/2024

Institution | **Educational Institution** | **ENCePP partner**

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

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2026

Actual: 01/07/2026

Study start date

Planned: 26/10/2026

Actual: 26/10/2026

Date of final study report
Planned: 26/02/2027

Sources of funding

- EMA

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

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.

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