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

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Administrative details

Contact details

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Primary lead investigator

PURI

https://redirect.ema.europa.eu/resource/106437

EU PAS number

EUPAS106436

Study ID

106437

DARWIN EU® study

Yes

Study countries

France Germany Spain United Kingdom

Study description

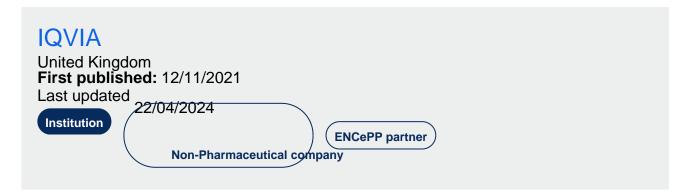
Systemic SLE erythematosus: SLE is a multisystem autoimmune disorder of connective tissue characterized by autoantibodies that target nuclear antigens, remissions and flares, and a highly variable clinical presentation, disease course, and prognosis. The disease course is more severe in childhood-onset 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 institution and networks

Institutions



Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

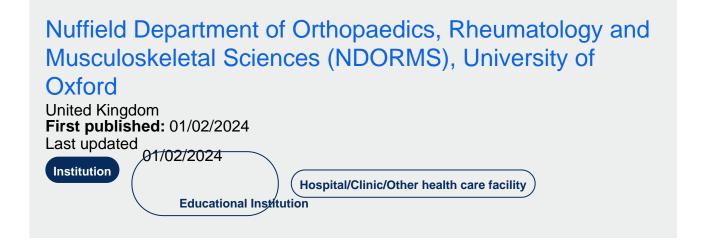
Spain

First published: 05/10/2012









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:

06/07/2023

Actual:

06/07/2023

Data collection

Planned:

01/01/2013

Actual:

01/01/2013

Date of final study report

Planned:

31/10/2023

Actual:

01/12/2023

Sources of funding

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 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

Study drug and medical condition

Name of medicine, 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

100000096035

betamethasone

100000096036

dexamethasone

100000096037

fluocortolone

100000096038

methylprednisolone

100000096039

paramethasone

100000096040

prednisolone

100000096041

prednisone

100000096042

triamcinolone

100000096043

hydrocortisone

100000096044

cortisone

100000096045

prednylidene

100000096046

rimexolone

100000096047

deflazacort

100000096048

cloprednol

100000096049

meprednisone

100000096050

cortivazol

100000096617

cyclophosphamide

100000096649

methotrexate

200000025810

rituximab

100000096853

mycophenolic acid

100000125042

belimumab

100000096879

ciclosporin

100000096880

tacrolimus

100000125044

voclosporin

100000096882

azathioprine

100000096884

methotrexate

100000097850

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.

Data management

Data sources

Data source(s)

Institut Municipal d'Assistència Sanitària Information System Disease Analyzer Germany The Information System for Research in Primary Care Clinical Practice Research Datalink (CPRD) GOLD Clinical Data Warehouse of the Bordeaux University Hospital

Data sources (types)

Administrative data (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

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No