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

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Study | Finalised

Administrative details

Contact details

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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

IQVIA
United Kingdom
First published: 12/11/2021
Last updated
22/04/2024
Institution
Non-Pharmaceutical company
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

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
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

- 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

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