A Non-Interventional Multi-Database Post-Authorisation Study to Assess PregnancyRelated Safety Data from Women with SLE Exposed to Anifrolumab (ROSE PASS)

First published: 16/01/2024

Last updated: 19/03/2025

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/199011

EU PAS number

EUPAS108728

Study ID

199011

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] United States

Study description

The aim of this study is to describe congenital malformations, adverse pregnancy and birth outcomes in pregnancies/offspring from women with moderate/severe SLE exposed to anifrolumab during pregnancy and to compare with outcomes in women with moderate/severe SLE who are exposed to other SOC but not anifrolumab. Adverse outcomes related to infant growth up to one year of age will also be investigated.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

- [ ] United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Ana Cristina Santos

Study contact

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Primary lead investigator

Ana Cristina Santos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/03/2022

Actual: 15/03/2022

Study start date

Planned: 31/05/2025

Date of final study report

Planned: 31/03/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

AZ SLE anifrolumab pregnancy PASS_Protocol v3.0_28Aug2023_redacted.pdf (2.4 MB)

AZSLEA~2.PDF(2.59 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Study design:

The study will utilise a non-interventional longitudinal population-based retrospective cohort
design. It will be conducted using secondary data derived from multiple databases which record
longitudinal medical data.

Main study objective:

The aim of this study is to describe major congenital malformations (MCM), adverse pregnancy, and birth outcomes in pregnancies/offspring from women with moderate/severe SLE exposed to anifrolumab and compare the occurrence of these outcomes to outcomes observed in women with moderate/severe SLE whose pregnancies were not exposed to anifrolumab

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

anifrolumab

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

ANIFROLUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG11) anifrolumab

anifrolumab

Medical condition to be studied

Systemic lupus erythematosus

Population studied

Short description of the study population

For MCM analysis, a total number of 732 live and non-live births (183 anifrolumab and 549 comparator) using a matching ratio of 1:3. For the select adverse pregnancy loss outcomes analysis, a total number of 244 pregnancies (61 anifrolumab and 183 comparator) using a matching ratio of 1:3 would be necessary.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

976

Study design details

Outcomes

The primary outcomes of interest are MCM (defined as a composite of all major MCMs) occurring in live or non-live offspring and select pregnancy loss outcomes (composite of spontaneous abortion and stillbirth), Minor congenital malformations (mCM), Adverse pregnancy outcomes, Adverse birth outcomes

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Data analysis plan

A full description of the analytical approach will be developed and described in the SAP. Also details on data derivations, category definitions, analyses, and presentation of the study results will be provided in SAP.

The SAP will be finalised prior to the conduct of the study analyses. All study results will be presented separately for each data source in the study reports, as appropriate when data become available.

The full study reports for all data sources, including all descriptive, comparative, exploratory, and sensitivity analyses, as well as the meta-analysis results will be provided in the final report.

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

National Health Data System - SNDS, Rheuma-Kindwunsch und Schwangerschaft - RHEKISS, HealthCore Integrated Research Database - HIRD United States, Finnish Registries, DAPI database

Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Pharmacy dispensing records, Hospital medication registries

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No