WEUKBRE6076: Benlysta Pregnancy Registry (BPR) - Prospective cohort study of pregnancy outcomes following Benlysta exposure within 4 months prior to and/or during pregnancy (114256)

First published: 19/05/2014

Last updated: 03/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6577

Study ID

50563

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium

- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Israel
- [ ] Italy
- [ ] Portugal
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United States

Study status

Finalised

Research institutions and networks

Institutions

Pharmaceutical Product Development (PPD)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/07/2011

Actual: 21/07/2011

Study start date

Planned: 16/07/2012

Actual: 16/07/2012

Date of final study report

Planned: 17/07/2023

Actual: 26/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-114256-protocol-am4-redact.pdf(3.35 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pregnancy registry

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To evaluate pregnancy and infant outcomes for pregnancies in women with systemic lupus erythematosus exposed to belimumab within the 4 months prior to and/or during pregnancy

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multi-center, prospective study

Study drug and medical condition

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

BELIMUMAB

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

The study population included pregnant women with systemic lupus erythematosus (SLE) exposed to belimumab within the 4 months prior to and/or during pregnancy.

Minimum criteria for enrolment will be the following:

- For belimumab exposed pregnant women: Sufficient evidence to confirm that exposure to commercially supplied belimumab occurred within the 4 months prior to and / or during pregnancy (“belimumab exposed”)

Or

- For belimumab unexposed pregnant women:

Any women who became pregnant during the SABLE protocol and was not exposed to belimumab: Sufficient evidence to confirm that exposure to belimumab did not occur within 4 months prior to and / or during pregnancy (“unexposed”)

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Birth defect prevalence, Infant outcomes and other pregnancy outcomes

Data analysis plan

Descriptive statistics will be performed for all prospective, evaluable data. The summary statistics for continuous and categorical variables to be used will be specified in the Reporting and Analysis Plan (RAP) but may include means, standard deviations, medians, minimums, maximums, percentiles, and percentages. Frequencies and proportions of adverse pregnancy outcomes, birth defects, serious and/or clinically significant infections in infants will be calculated with corresponding 95% confidence intervals. For the primary endpoint of birth defect prevalence, the estimates of birth defect prevalence from MACDP and EUROCAT will be used to represent external population comparators. The differences between the observed registry birth defect rates and these comparators will be estimated along with 95% confidence intervals.

Documents

Study results

Synopsis_Anonymized.pdf(525.85 KB)

Study publications

Juliao P, Wurst K, Pimenta JM, Gemzoe K, Landy H, Moody MA, Tilson H, Covington…

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 sources (types)

Other

Data sources (types), other

Exposure registry

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