The Belimumab Pregnancy Exposure Study: An OTIS Autoimmune Diseases in Pregnancy Project (213928)

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Study Ongoing

Administrative details

EU PAS number

EUPAS49554

Study ID

50568

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study status

Ongoing

Research institutions and networks

Institutions

GlaxoSmithKline (GSK)

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/10/2020

Actual: 29/10/2020

Study start date

Planned: 14/12/2022

Actual: 14/12/2022

Date of final study report
Planned: 31/05/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GSK

Study protocol

Protocol_Approved_Final_Anonymized.pdf (1.41 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:

Safety study (incl. comparative)

Main study objective:

To evaluate belimumab exposure in pregnancy with respect to major birth defects when compared to the background rate in an unexposed SLE cohort.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BENLYSTA

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

BELIMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA26) belimumab

belimumab

Medical condition to be studied

Systemic lupus erythematosus

Population studied

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Special population of interest

Pregnant women

Estimated number of subjects

11

Study design details

Outcomes

To monitor planned and unplanned pregnancies exposed to belimumab and to evaluate the possible teratogenic effect of this medication relative to the primary pregnancy outcomes of major birth defects. Secondary outcomes also evaluated in the study include other pregnancy outcomes as well as infant outcomes up to one year of age.

Data analysis plan

The primary comparison will be the proportion of major structural defects between the exposed group (Cohort 1) and the diseased comparison group (Cohort 2) among pregnancies resulting in at least one live born infant. A point estimate of the crude (i.e. unadjusted) risk ratio (RR) of the exposed group versus the unexposed group, as well as its 95% confidence interval (CI) will be computed using the normal approximation method. When the expected frequency of any of the cells of the contingency table is less than five, the CI will be obtained by an exact method using the software Stat XACT, the method is based on invertingNe an unconditional exact hypothesis test. The comparison

will also be carried out within each of two strata, according to whether the woman had prenatal diagnostic testing, such as level II ultrasound, amniocentesis or chorionic villus sampling, prior to enrollment in the study or not.

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

Spontaneous reporting system, 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