A Registry-Based Observational Study to Assess Maternal, Pregnancy, and Infant Outcomes Following Exposure to Ixekizumab (I1F-MC-B010)

First published: 05/11/2021

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Study Planned

Administrative details

EU PAS number

EUPAS32751

Study ID

32752

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

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Study contact

elgrace@lilly.com

Primary lead investigator

Elsie Grace

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/10/2018

Study start date

Planned: 31/12/2021

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Co.

Study protocol

I1F-MC-B010(b) PASS Protocol_Redacted.pdf (3.76 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To estimate the relative birth prevalence of major congenital malformations (up to 12 months) among infants born to women exposed to ixekizumab during the first trimester of pregnancy as compared to similar women who are (a) exposed to a TNF inhibitor during the first trimester of pregnancy, or (b) unexposed to biologics or other systemic disease modifying anti-rheumatic drugs during pregnancy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IXEKIZUMAB

Medical condition to be studied

Psoriasis

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

716

Study design details

Outcomes

Major congenital malformations, Pregnancy, infant, and maternal outcomes

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Data analysis plan

Descriptive analyses will be generated for all enrolled women and infants. Baseline tables will describe attrition, timing of exposure, number of pregnancies with known outcome at time of enrollment, the number of women with prenatal screening prior to enrollment, and the mother’s baseline characteristics. A descriptive summary of study outcomes will also be provided, with serious infections and malformations presented as composite and individual outcomes. Comparative analyses will be conducted separately for each outcome and will include adjustment for confounding and any relevant sensitivity analyses. For all comparative analyses, ixekizumab will be the treatment of interest. The TNFi and unexposed cohorts will be the reference cohorts. Comparative analyses will be performed once there is adequate power, or for the final report, whichever comes first. The point estimate and precision

for each outcome will be provided.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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