Observational Study to Assess Maternal and Fetal Outcomes Following Exposure to Ixekizumab (I1F-MC-B005)

First published: 29/01/2018

Last updated: 22/04/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28013

EU PAS number

EUPAS15481

Study ID

28013

DARWIN EU® study

No

Study countries

☐ United States

Study status

Planned

Research institutions and networks

Institutions

HealthCore

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Grace Elsie

Study contact

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Primary lead investigator

Grace Elsie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/02/2016

Study start date
Planned: 31/03/2018

Date of final study report
Planned: 30/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

ELI_Pregnancy_Safety_Protocol_Redacted.pdf(439.29 KB)

B005 PASS(2)_Redacted.pdf(776.84 KB)

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

To monitor the uptake of ixekizumab among women of childbearing age (ages 15-45), and monitor the incidence of maternal and fetal/infant outcomes among pregnant women exposed to ixekizumab. If sufficient exposures are identified, an additional objective is to study maternal and fetal/infant outcomes among pregnant women exposed to ixekizumab compared to similar women treated with TNF-α inhibitors.

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)

Infants and toddlers (28 days – 23 months)

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

830

Study design details

Outcomes

Major congenital malformations of the infant. Pregnancy outcomes: Recognized spontaneous abortions, stillbirths, elective terminations, preterm delivery, and small for gestational age infants.Infant outcomes: Minor congenital anomalies (up to 12 months of age) and serious infections of the infant (up to six months of age).Maternal outcomes: Serious infections during pregnancy and serious peri-partum infections.

Data analysis plan

The number of ixekizumab exposures and outcomes among exposed mother-infant pairs will be provided. If a sufficient number exposures are identified for comparative analysis, incidence rate ratios and birth prevalence ratios (as applicable) and their 95% CI will be calculated comparing ixekizumab exposed pregnancies versus comparator TNF-α inhibitor biologic exposed pregnancies.

Sensitivity analyses are planned.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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