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

First published: 29/01/2018

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Study Planned

Administrative details

EU PAS number

EUPAS15481

Study ID

28013

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

HealthCore

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Institution

Contact details

Study institution contact

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Study contact

carragher_natacha@lilly.com

Primary lead investigator

Natacha Carragher

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 list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This administrative claims-based cohort study of ixekizumab exposure during pregnancy will
include two phases. Phase I: Uptake monitoring. Phase II: Cohort surveillance.

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

Anatomical Therapeutic Chemical (ATC) code

(L04AC13) ixekizumab

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

Comparators

Comparator group of IL inhibitor medications; guselkumab, secukinumab, brodalumab, and ustekinumab

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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

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)

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