Observational Study of Pregnancy and Infant Outcomes Among Women Exposed to Mirikizumab During Pregnancy in US-based Administrative Claims Data (I6T-MC-B003)

First published: 03/10/2023

Last updated: 10/12/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105675

EU PAS number

EUPAS105674

Study ID

105675

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Aetion

Spain

First published: 24/11/2022

Last updated: 16/07/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

Francis Mawanda

Study contact

mawanda_francis@lilly.com

Primary lead investigator

Francis Mawanda

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/05/2023

Study start date
Planned: 26/05/2025

Date of final study report
Planned: 31/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3074828 B003 Protocol Version 1_Redacted (1).pdf(1.87 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Describe the occurrence of adverse pregnancy & infant outcomes among pregnant women with ulcerative colitis who are exposed to mirikizumab & infants linked to those mothers & in women with ulcerative colitis exposed to comparator medications.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

OMVOH

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

MIRIKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC24) mirikizumab

mirikizumab

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

426 mirikizumab-treated patients and their mother-infant linked pregnancies

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

426

Study design details

Outcomes

Major congenital malformations, Spontaneous abortions, stillbirth, preterm birth, small for gestational age

---

Data analysis plan

Dichotomous & categorical covariates will be summarized using counts with percentages, & non-missing values of continuous variables will be summarized using means with standard deviations & medians with interquartile range. Counts of outcomes will be presented, along with timing of exposure to mirikizumab or comparator group treatments. The prevalence of each outcome will be reported as count per 100 pregnancies or live births along with the 95% confidence intervals. Additionally, incidence rates will be reported for the major congenital malformation outcome. Crude and propensity score adjusted relative risks (95% CI) will be estimated by robust (modified) Poisson regression using a log link and a Poisson distribution without an offset parameter. Several sensitivity analyses will be conducted to test robustness of results to study specifications.

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