

# 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

### EU PAS number

EUPAS105674

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### Study ID

105675

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### DARWIN EU® study

No

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### Study countries

 United States

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### 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 [mawanda\\_francis@lilly.com](mailto:mawanda_francis@lilly.com)

Study contact

[mawanda\\_francis@lilly.com](mailto:mawanda_francis@lilly.com)

### Primary lead investigator

Francis Mawanda

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 09/05/2023

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### Study start date

Planned: 26/05/2025

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### **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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**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

**Medicinal product name**

OMVOH

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

MIRIKIZUMAB

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## **Anatomical Therapeutic Chemical (ATC) code**

(L04AC24) mirikizumab

mirikizumab

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## **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

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### **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)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

426

## Study design details

## Outcomes

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

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## 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

### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No