Mirikizumab Pregnancy Registry (I6T-MC-B006)

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Administrative details

EU PAS number
EUPAS107688
Study ID
107689
DADWIN FILE study
DARWIN EU® study
No
Study countries
United States
Study description
Mirikizumab Pregnancy Registry

Planned

Study status

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Contact details

Study institution contact

Francis Mawanda mawanda_francis@lilly.com

Study contact

mawanda_francis@lilly.com

Primary lead investigator

Francis Mawanda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/12/2023

Study start date

Planned: 31/03/2025

Date of final study report

Planned: 31/12/2035

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Eli Lilly & amp, Co.

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

To estimate the relative birth prevalence of major congenital malformations (up to 12 months) among infants born to women exposed

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

Population studied

Age groups

- Preterm newborn infants (0 27 days)
- Term newborn infants (0 27 days)
- Infants and toddlers (28 days 23 months)
- Adults (18 to < 46 years)

Estimated number of subjects

400

Study design details

Outcomes

Major congenital malformations

Data analysis plan

Descriptive analyses will be generated for all enrolled women and infants.

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The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Unknown Check completeness Unknown

Check stability

Check conformance

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No