Mirikizumab Pregnancy Registry (I6T-MC-B006)

First published: 15/12/2023

Last updated: 28/10/2024

Study Planned

Administrative details

EU PAS number

EUPAS107688

Study ID

107689

DARWIN EU® study

No

Study countries

☐ United States

Study description

Mirikizumab Pregnancy Registry

Study status

Planned

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

Data sources

Data sources (types)

Other

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