Observational Secondary Database Study to Assess the Long-Term Safety of Mirikizumab (I6T-MC-B004)

First published: 03/10/2023

Last updated: 22/11/2024

Study Planned

Administrative details

EU PAS number

EUPAS105671

Study ID

105672

DARWIN EU® study

No

Study countries

United States

Study status

Planned

Research institutions and networks

Institutions

Optum

Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

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: 17/05/2023

Study start date

Planned: 26/05/2025

Date of final study report
Planned: 31/12/2037

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3074828 B004 Protocol Draft 2_ENCePP_Redacted.pdf (1.04 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

Drug utilisation

Main study objective:

To examine the incidence of MACE, malignancies excluding non-melanoma skin cancer, serious and opportunistic infections, and severe liver injury among patients who are treated with mirikizumab relative to those treated with comparator biologic medications that are indicated for the treatment of moderate to severe ulcerative colitis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

5000

Study design details

Outcomes

MACE, serious and opportunistic infections, malignancies, and severe liver injury

Data analysis plan

Comparative analyses will employ Cox proportional hazards models of the relative hazard of study outcomes in mirikizumab patients versus their matched comparators, as well as descriptive analyses

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