

# The Risk of Serious Infections with Mirikizumab versus Other Biologics among Patients with Ulcerative Colitis: A Secondary Database Study in Japan

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000338

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### Study ID

1000000338

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### DARWIN EU® study

No

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### Study countries

Japan

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### Study description

On 27 March 2023, mirikizumab, a monoclonal antibody that binds to and inhibits IL-23, was authorized in Japan for the treatment of adult patients with moderate to severe ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to conventional therapy.

It is reported that UC is associated with an increased risk of infections partially due to impairments of the immune system and use of immunosuppressive medications. Although no increased risk of serious infections comparing mirikizumab and placebo was observed among patients with UC in phase 3 clinical trials, mirikizumab may increase the risk of infections given its pharmacological mechanisms. Furthermore, it is largely unknown whether mirikizumab use, compared with other biologics, is associated with an increased risk of serious infections in routine clinical practice.

Therefore, the objective of this safety study is to examine the incidence of serious infections among patients with a diagnosis of UC who are exposed to mirikizumab compared to patients with a diagnosis of UC who are exposed to other biologics indicated for the treatment of UC in real world clinical practice in Japan.

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## **Study status**

Planned

## Research institutions and networks

### Institutions

[Eli Lilly and Company](#)

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Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Jiayi Dong

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 21/06/2023

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### Study start date

Planned: 30/11/2026

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### Date of final study report

Planned: 30/06/2028

## Regulatory

## Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

## 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:**

Safety study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

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#### **Study design:**

This study will employ an incident new user design, limiting the study population to patients who are new users of mirikizumab or the comparator biologic during the patient identification period.

**Main study objective:**

The objective of this study is to describe the incidence of serious infections and estimate the hazard ratio for serious infections among adult patients 18 years of age and older with a diagnosis of UC who are exposed to mirikizumab versus their propensity score-matched comparators (TNF inhibitors, vedolizumab, or ustekinumab) using Cox proportional hazard models.

## 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

The source population will consist of patients with a diagnosis of UC who are in the claims-based MDV database and have at least one prescription of mirikizumab or a comparator biologic during the patient identification period.

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## Age groups

- **Adult and elderly population ( $\geq 18$  years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly ( $\geq 65$  years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

## Study design details

### Setting

The source population will consist of patients with a diagnosis of UC who are in the claims-based MDV database and have at least one prescription of mirikizumab or a comparator biologic during the patient identification period (i.e., on or after 21 June 2023 through 31 May 2026).

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### Comparators

Three individual comparator cohorts (TNF inhibitor cohort, vedolizumab cohort, and ustekinumab cohort) will be created.

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### Outcomes

### **Data analysis plan**

Propensity score (PS) matching will be used to balance the covariates between the mirikizumab and comparator cohorts. Three logistic regression models will be used to calculate the propensity of receiving mirikizumab versus receiving (1) a TNF inhibitor, (2) vedolizumab, or (3) ustekinumab.

Each patient in the mirikizumab cohort will be matched with up to 3 patients in the comparator cohort (1:3) based on the PS using nearest neighbour matching (calliper width 0.2 of the standard deviation of the logit score).

Incidence rates of serious infections in matched mirikizumab and comparator cohorts will be computed, defined as number of cases divided by the total person-years of follow-up in each comparison set.

Cox proportional hazard models will be used in all association analyses to estimate hazard ratios and corresponding 95% confidence intervals of serious infections among mirikizumab users compared to PS-matched users of: (1) TNF inhibitors, (2) vedolizumab, and (3) ustekinumab, separately.

## 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.

## 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