A Non-interventional Observational Longitudinal Post-Authorization Safety Study (PASS) of SIMPONI® in Treatment of Ulcerative Colitis using Nordic National Health Registries (MK-8259-013)

First published: 09/11/2015

Last updated: 09/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS11484

Study ID

50508

DARWIN EU® study

No

Study countries

Denmark

Sweden

Study description

Simponi received European marketing authorization for treatment of moderately to severely active ulcerative colitis (UC) on 19-Sep-2013. This registry-based study is being established as a post-marketing commitment to provide additional information on colorectal cancer (CRC), colectomy, and hepatosplenic T-cell lymphoma (HSTCL), as outlined in the Risk Management Plan for SIMPONI® that was approved with authorization of the UC indication.

Study status

Finalised

Research institutions and networks

Institutions

Institute of Applied Economics and Health Research (ApHER)

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Institution

The Institute for Public Health at University of Southern Denmark 1353 Copenhagen, Denmark Centre for Health Economics at Gothenburg University Vasagatan 1, Gothenburg, Sweden

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Anders Green

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/11/2015

Actual: 09/12/2015

Study start date

Planned: 01/12/2015

Actual: 07/02/2017

Data analysis start date

Planned: 31/03/2022

Actual: 15/02/2022

Date of final study report

Planned: 30/09/2023

Actual: 26/09/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD, Janssen

Study protocol

MK-8259-013-00 Protocol Summary.pdf (1.24 MB)

MK-8259-013-01v2-Prot_Final Redaction.pdf (676.17 KB)

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

Disease epidemiology

Drug utilisation

Main study objective:

To characterize the clinical and demographic profile of first-time users of golimumab (GLM) vs first time users of alternate therapies in the treatment of UC, to describe the risk of incident CRC and the risk of all-cause total colectomy exposed to GLM and alternative therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SIMPONI

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

GOLIMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AB06) golimumab

golimumab

Medical condition to be studied

Colitis ulcerative

Colorectal cancer

Hepatosplenic T-cell lymphoma

Colectomy

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

3000

Study design details

Outcomes

Incidence of CRC, incidence of all-cause total colectomy

Data analysis plan

Patients in each cohort will be followed for the outcomes of CRC, HSTCL, and colectomy through 18- Mar-2021. The risk of primary outcomes (incident CRC,

all-cause total colectomy) will be estimated as cumulative incidence within each inception cohort in unadjusted and adjusted analyses. Censoring events will include death, emigration, and first occurrence of study outcomes. The cohort analyses will be conducted based on automated data only using survival analysis techniques (including Kaplan-Meier) to estimate cumulative risks. Sensitivity analyses have been specified that examine the robustness of results to alternate specifications of the study population, risk window, outcome definitions, and additional adjustment using quantitative bias analysis (QBA).

Documents

Study report

MK-8259-013-CSR-Final-Report-may-2024-final-redaction.pdf (3.37 MB)

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 source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

National Patient Register, Sweden

Danish Civil Registration System, Denmark

Swedish Cause of Death Registry, Sweden

Danish National Prescription Registry, Denmark

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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