A Post-Authorization Safety Study of Golimumab in Ulcerative Colitis Using the Spanish ENEIDA Registry

First published: 10/10/2016

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50619

EU PAS number

EUPAS15752

Study ID

50619

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) of unknown etiology that may be associated with severe symptoms and impaired quality of life. UC may affect all ages and medical treatment depends on disease severity and extent. In the case of intractable disease, colectomy may be indicated. Patients with UC are at increased risk of developing colorectal cancer (CRC) and dysplasia compared to the general population. Simponi (golimumab; GLM) received European marketing authorization for treatment of moderately to severely active ulcerative colitis on 19-Sep-2013. This long-term, non-interventional observational study will use data from ENEIDA, a large prospectively maintained registry of patients with IBD in Spain to evaluate whether the use of GLM is associated with a risk of colectomy for intractable disease, advanced neoplasia (colorectal cancer or high grade dysplasia), and Hepatosplenic T-Cell Lymphoma (HSTCL) in patients with UC as compared with alternative therapies for similar severity of disease. It will use a new user bi-directional cohort design with the option for a nested case-control (NCC) analysis. The cohort study will use data that are primarily collected for the Spanish ENEIDA IBD registry, and the NCC analysis will also use data from retrospective review of selected medical charts.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

Multiple centres: 30 centres are involved in the study

Networks

Grupo Español Trabajo en Enfermedad de Crohn y Colitis Ulcerosa (GETECCU)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Joan Fortuny

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/02/2016

Actual: 29/02/2016

Study start date

Planned: 20/09/2016

Actual: 20/09/2016

Data analysis start date

Planned: 31/10/2022

Actual: 01/06/2022

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

Merck Sharp & Dohme LLC

Study protocol

MK8259-042-00_Redacted.pdf(3.39 MB)

MK8259-042-00_v1.1_Redacted.pdf(1.28 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

This study seeks to evaluate whether the use of GLM is associated with a risk of colectomy for intractable disease, advanced neoplasia (colorectal cancer or high grade dysplasia), and HSTCL in patients with UC as compared with alternative therapies for similar severity of disease. No a priori hypotheses will be evaluated.

Study Design

Non-interventional study design

Case-control

Cohort

Other

Non-interventional study design, other

Long-term observational, post-authorization safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB06) golimumab

golimumab

Medical condition to be studied

Colitis ulcerative

Population studied

Short description of the study population

The study population comprised of patients aged 18 years or older diagnosed with ulcerative colitis (UC) received treatment with golimumab (GLM), an anti-TNF agent other than GLM, or thiopurine between 19 September 2013 (date of GLM EU approval for UC) through 31 December 2021 identified from the ENEIDA registry.

Inclusion Criteria:

• Patient with UC in a research-quality site.

• Aged 18 years or older at the date of study drug initiation.

• Qualified for one of the cohorts between 19 September 2013 and 31 December 2021.

• Date of first prescription of cohort-defining drug (index date) occurred within a clinically credible period (< 6 months) after the last recorded clinic visit in ENEIDA. Index dates beyond this range raise concerns that the clinical record for this patient may be incomplete.

Exclusion criteria:

• Initiation of study drugs for indications other than UC, such as rheumatoid arthritis or psoriasis.

• Evidence of any of the study outcomes before cohort entry:

o Complete or partial colectomy

o ACN

o HSTCL

• For each of the 3 cohorts (ie, GLM, other anti-TNF, and thiopurine), if the patient initiated the drug defining the corresponding cohort for the first time before 19 September 2013. In other words, patients did not qualify for entry into a cohort if they were prevalent users of that drug before the study start date. However, patients could enter the study later based on subsequent initiation of other cohort-defining drugs.

• If, prior to cohort entry, patients had initiated a novel biological or immunomodulator agent, for example:

o Vedolizumab: Entyvio®

o Natalizumab: Tysabri®, Antegren®

o Denosumab: Prolia®, Xgeva®

o Etrolizumab: Raptiva®

o Tocilizumab: Actemra®, RoActemra®

o Ustekinumab: Stelara®

o Certolizumab: Cimzia®

o Tofacitinib: Xeljanz®

This list defines the drugs referred to as “vedolizumab and other novel immunomodulators” mentioned in the protocol and covers drugs that would likely be prescribed to patients with more severe UC and that are potentially related to the study outcomes.

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)

Special population of interest

Other

Special population of interest, other

Patients with ulcerative colitis

Estimated number of subjects

3200

Study design details

Outcomes

Colectomy due to intractable disease, Composite advanced colonic neoplasia (Colorectal cancer or High-grade colorectal dysplasia), Colorectal Cancer, Hepatosplenic T-cell Lymphoma

Data analysis plan

All analyses will be conducted based on automated registry data, except for the nested-case control analysis. Baseline analyses will describe each cohort by patient characteristics. For each inception cohort, annual enrolment will be described, along with the frequency of study outcomes and cumulative person-years of follow-up accrued. The incidence rate of primary and secondary outcomes will be estimated for each inception cohort. The cumulative incidence of primary and secondary outcomes will be estimated using time-to-event analyses, overall by inception cohorts and then in stratified analyses. Stratification factors will be evaluated one at a time and will include gender, time since initial UC diagnosis, history of primary sclerosing cholangitis, UC hospitalization, and previous use of systemic steroids. Separate nested case-

control analyses are planned to evaluate the association between study exposures and the two primary outcomes, colectomy for intractable disease and ACN.

Documents

Study results

ISRR-ReportBody-MK-8259-042-947763 - Redacted.pdf(4.7 MB)

Study publications

Fortuny J, Rasouliyan L, Mines D, Tormos A, Earley E, Pérez-Gutthann S, Domènec…

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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