MLN-0002_401: Entyvio (vedolizumab) long-term safety study: An international observational prospective cohort study comparing vedolizumab to other biologic agents in patients with ulcerative colitis or Crohn’s Disease (Entyvio PASS study)

First published: 27/05/2014

Last updated: 24/10/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6469

Study ID

48143

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Canada
- [ ] Croatia
- [ ] Denmark
- [ ] Estonia
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom
- [ ] United States

Study description

This study is a non-interventional prospective cohort study to compare the safety of long-term treatment with vedolizumab, with the safety of long-term treatment with other biologic agents for ulcerative colitis (UC) or Crohn's Disease (CD). 5,000 patients will be recruited and followed for up to 7 years, with 6-monthly clinic visits at which information will be collected on adverse events, UC/CD disease management, and comorbidities.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda trialdisclosures@takeda.com

Study contact

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Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/12/2013

Study start date
Planned: 01/02/2015

Actual: 24/03/2015

Data analysis start date
Planned: 30/07/2021

Actual: 03/08/2021

Date of final study report
Planned: 20/06/2022

Actual: 15/06/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab PASS study (MLN-002-401) protocol Final_v1_2.pdf(437.28 KB)

MLN0002_401-Protocol-V3.1-Redacted.pdf(7.91 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:

Primary data collection

Main study objective:

To assess the long-term safety of vedolizumab versus other biologic agents in patients with Ulcerative Colitis or Crohn's Disease.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, observational, multi-center study

Study drug and medical condition

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

VEDOLIZUMAB

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

Patients with UC or CD who were initiating vedolizumab therapy were recruited into the vedolizumab cohort. Patients may have had prior exposure to biologics or were naïve to biologics. Patients were to be naïve to vedolizumab at study

entry. Patients with UC or CD who initiated therapy with another biologic agent indicated for UC or CD were recruited into the other biologic agents cohort. Patients may have had prior exposure to biologic agents or were naïve to biologics. Patients may not have had prior exposure to vedolizumab at study entry.

Inclusion Criteria:
- Signed informed consent, by the patient or a legally acceptable representative, obtained before any study-related activities were undertaken.
- Male and female patients, aged at least 18 years.
- Initiated vedolizumab or initiated a biologic agent for UC or CD (where possible patients were recruited on or before day of first dose of vedolizumab or other biologic agent. To help fit recruitment around busy clinics, patients were recruited up to 2 weeks after first dose of vedolizumab or other biologic).
- Signed release form, by the patient or a legally acceptable representative, that permitted abstraction of the patient’s medical records at baseline and during participation in the study.
Exclusion Criteria:
- The patient was enrolled in a clinical trial in which treatment for UC or CD was managed through a protocol.
- Prior treatment with vedolizumab

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

Immunocompromised

Pregnant women

Estimated number of subjects

5000

Study design details

Outcomes

The primary outcome measures is serious infections (infections that are SAEs and opportunistic infections such as PML). The secondary safety outcomes include: gastrointestinal infections, respiratory infections, malignancies, hepatic injury, and hypersensitivity. Effectiveness endpoints include change in disease severity, change in biomarker levels, use of corticosteroids, IBD-related surgery, use of health care resources, and change in patient reported outcomes.

Data analysis plan

The primary safety analysis will focus on serious infections. Secondary analyses will look at individual serious infections, including PML, and the other Adverse Events of Special Interest. The safety analyses will present number of events, person-years of follow-up and crude incidence rates in each cohort. Time varying Cox proportional hazard models, with propensity score stratification will be used to generate adjusted hazard ratios. Analyses will be presented for all patients, and separately for UC and CD patients. Multivariate analysis with adjustment for confounders will assess risks with respect to duration of use, cumulative dose, and time since first use of vedolizumab. Other SAEs, adverse reactions and pregnancy data will be summarized by cohort with stratification by baseline characteristics.

Documents

Study results

MLN-0002_401 RDS Amended 9May2023.pdf(787.08 KB)

MLN0002_401_RDS_11Jul2022.pdf(715.37 KB)

MLN0002_401-clinical-study-report-redact.pdf(781.51 KB)

Study, other information

MLN0002_401 PASS protocol version 3 (Belgium- web without FACIT) 14 Sept 2015.pdf(1.92 MB)

MLN0002_401 PASS protocol version 3 (Canada) 14 Sept 2015.pdf(1.82 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 sources (types)

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