Vedolizumab-5050: Clinical Perspective of Vedolizumab (Entyvio) use in the Drug Program "Vedolizumab in the Treatment of Ulcerative Colitis" (POLONEZ)

First published: 20/04/2020

Last updated: 24/06/2022

Study | Finalised

Administrative details

EU PAS number

EUPAS34119

Study ID

47738

DARWIN EU® study

No

Study countries

Poland

Study description

This is a prospective, non-interventional, national, multi-center study. This study will assess 54-week safety and effectiveness in patients with ulcerative colitis (UC) who are eligible for Drug Program (DP) treatment with vedolizumab in Poland. DP is a reimbursement program authorized by Ministry of Health in this country to grant patients access to highly specialized therapies, example biologics, such as vedolizumab. The study is based on data collection from all patients enrolled for treatment in DP between February 2019 and April 2020. All patients will be enrolled in one Cohort, where patient will receive vedolizumab as per local prescribing information and DP inclusion and exclusion criteria at Visit 1 (Week 0), Visit 2 (Week 14) and Visit 3 (Week 54) or until termination. The follow up Visit 4 (Week 80) will be performed in patients who completed the full treatment schedule within DP. The study will enroll approximately 100 patients who initiated treatment with vedolizumab. The study is planned to be conducted in Poland. The overall duration of this study is approximately 2 years and 5 months.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Multiple centres: 13 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Edyta Zagorowicz

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 14/12/2017

Study start date

Actual: 28/02/2019

Data analysis start date

Actual: 06/07/2021

Date of interim report, if expected

Actual: 03/02/2020

Date of final study report
Actual: 06/05/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-5050_Protocol_redacted.pdf (1.36 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to assess the clinical data for effectiveness (response rate and remission rate) of vedolizumab in patients with UC administered the drug in the scope of DP.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, non-interventional, national, 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

Population studied

Short description of the study population

The study population included consecutive patients aged 18 years or older with UC who were initiating vedolizumab treatment in DP.

The patient had to meet all of the following criteria to be eligible for recruitment in the study:

1. Informed consent signed by the patient, obtained before any study-related activities are undertaken

2. Age 18 years or more at the time of first VDZ infusion

3. Moderate to severe UC, Mayo score > 6 (range 0-12)

4. Insufficient response to conventional therapy, including steroids and mercaptopurine or azathioprine, or

- intolerant to conventional therapy, including steroids and mercaptopurine or azathioprine, or
- existing contraindication to conventional therapy, including steroids and mercaptopurine or azathioprine, or
- TNF-α inhibitor failure, defined as primary lack of response or loss of response to TNF-α inhibitor (lack of improvement in partial Mayo score (0-9) of at least 3 or 30% from baseline with concomitant lack of improvement in bleeding in partial Mayo score of at least 1 or lack of improvement in residual bleeding of at least 2), or

- adverse drug reactions to TNF-α inhibitor with imply inability to continue the treatment.

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

Estimated number of subjects

100

Study design details

Outcomes

The primary endpoint will include percentage of patients achieving response or remission on Week 54. The secondary endpoint will include disease activity using mayo score or partial mayo score, disease extent, electronic information management system (EIMs) concomitant treatment, steroids and its discontinuation, immunomodulators, past biological therapies including its number and outcomes, past hospitalization due to UC including number and duration, comorbidities and safety.

Data analysis plan

Standard descriptive statistic methods will be used which comprise the number of patients, arithmetic mean, standard deviation, minimum, median and

maximum. For categorical variables tables of frequencies (absolute and relative frequencies) will be presented. The difference in proportion of response and remission rates after 54 weeks of treatment and subsequently after 6 months of forced discontinuation of the drug administration will be statistically compared. The safety endpoints will be presented as incidence rate calculated using person-time analyses. Reported adverse events will be coded using Medical Dictionary for Regulatory Activities (MedDRA) dictionary and all adverse event summaries will present preferred terms and System Organ Class. Where appropriate 95 percent (%) confidence intervals will be provided.

Documents

Study results

Vedolizumab-5050_RDS_2022-06-14.pdf (687.3 KB)

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, Patients’ medical records

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