Vedolizumab-4024: A Multi-center, Longitudinal, Observational Study of the Effectiveness of Vedolizumab on Clinical Outcomes and Health-Related Quality if Life in Biologic Naive Patients with Inflammatory Bowel Diseases in Serbia Over a 2-year Period

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Study Ongoing

Administrative details

EU PAS number

EUPAS32913

Study ID

45090

DARWIN EU® study

No

Study countries

☐ Montenegro

☐ Serbia

Study description

This is a non-interventional, longitudinal, prospective, and multi-centre study. This study will assess the long-term benefit in bio-naive patients who are initiating the treatment with vedolizumab for ulcerative colitis (UC) and Crohn's disease (CD). Patients will receive treatment with vedolizumab under standard clinical practice and will be observed prospectively for 2 years, or until discontinuation of vedolizumab treatment, whichever occurs earlier. The study will review the medical charts of patients to evaluate the effectiveness of treatment with vedolizumab. The study will enroll approximately 140 patients (70 patients with moderately to severely active UC and 70 patients with moderately to severely active CD) who initiated treatment with vedolizumab. The study is planned to be conducted in Serbia. The overall duration of data collection in this study is approximately 2 years after enrollment in the study.

Study status

Ongoing

Research institutions and networks

Institutions

Takeda

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Institution

Aleksandar Biljic Erski

Clinical Center of Serbia Belgrade, Clinical Hospital Center Zvezdara Belgrade, Clinical Hospital Center Dragisa Misovic Belgrade, Clinical Hospital Center Zemun Belgrade, Clinical Hospital Center Bezanijska Kosa Belgrade, Clinical Center of Vojvodina Novi Sad, Clinical Center of Kragujevac Kragujevac, Clinical Center of Nis Nis, Clinical centre of Montenegro Podgorica

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jovana Cimbur

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/04/2020

Study start date
Planned: 01/04/2021

Actual: 19/04/2021

Data analysis start date
Planned: 01/08/2022

Date of final study report
Planned: 01/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the study is to assess long-term clinical benefit by means of drug discontinuation rate for the biologic-naive patients with inflammatory bowel disease treated with vedolizumab over a duration of 2 years.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal 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

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

140

Study design details

Outcomes

Primary outcome will include the drug discontinuation rates in UC and CD patients treated with vedolizumab in the two years follow-up period. Reasons for discontinuation will be collected. Clinical remission and response, change from baseline in Euro quality of life (Qol)-5 Dimension (EQ-5D) questionnaire, rates of dose intensification, discontinuation of corticosteroids in patients using steroids at baseline, impact of treatment with vedolizumab on clinical or patient-reported outcomes (PROs), endoscopic remission, use of biomarkers, safety profile of vedolizumab.

Data analysis plan

The analysis will be descriptive. All categorical variables will be listed and illustrated by absolute and relative frequencies. Continuous variables will be expressed as means, standard deviation (SD), median and range. For primary outcome, the percentage of patients among biologic naïve UC patients and among biologic naïve CD patients that discontinue treatment with vedolizumab within the two years follow up period will be reported, followed by the corresponding 95% confidence interval. For secondary outcomes, similarly, continuous variables will be described as means, standard deviations and quartiles and categorical variables will be summarized as frequencies and percentages.

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

Data will be collected from patients’ medical charts using case report forms (CRF).

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