Vedolizumab-4018: Observational Study of the Effectiveness of Vedolizumab on Treatment Outcomes and HRQoL in biologic naïve Patients with Inflammatory Bowel Diseases in Greece (TROVE)

First published: 11/05/2018

Last updated: 30/10/2025

Study | Finalised

Administrative details

EU PAS number

EUPAS23580

Study ID

46995

DARWIN EU® study

No

Study countries

Greece

Study description

This is a prospective, observational, multi-center and a cohort study of biologic naïve patients with moderate to severe ulcerative colitis (UC) or Crohn’s disease (CD) who have had an inadequate response with, lost response to, or were intolerant to conventional therapy. This study will assess long-term clinical benefits in patients who are initiating treatment with vedolizumab. Patients that are initiated on treatment with vedolizumab will be recruited into cohorts of UC or CD. This study will enroll approximately 200 patients (100 patients with UC and 100 with CD) into 2 cohorts who have initiated a treatment with vedolizumab in a clinical practice. The study will be conducted at 23 sites in Greece. The data will be collected for up to 2 years or until discontinuation of vedolizumab treatment, whichever occurs earlier after enrolment in the study.

Study status

Finalised

Research institutions and networks

Institutions

Sotiria Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

3rd Academic Dpt. of Internal Medicine,GI-Unit

1st Pathological Area, Pathological Clinic, Rio Hospital, Kymothois Crossroad 6, Patras, Gastroenterology Clinic of Medical School of University of Athens, Laiko Hospital, Agiou Thoma 17, Athens Greece, Gastroenterology Clinic, Alexandra Hospital, Lourou 1, Athens, Endoscopic-Operational Departmet, Iatriko Kentro Athinon, Distomou 5, Marousi, Athens Greece, Gastroenterology Clinic of Medical School of University of Larisa, Panepistimiou 3, Larisa, Gastroenterology Clinic, Theageneio Hospital, Al.Papanastasiou 11, Thessaloniki Greece, Gastroenterology Clinic A, Euaggelismos Hospital, Ipsilantou 45, Athens, Gastroenterology Clinic, Metropolitan Hospital, E.Makariou 1, Peiraias Greece, Pathological Department, Gastroenterology Clinic, Univ. Hospital of Ioannina, L. Stavrou Niarxou, Ioannina, B Pathological Clinic, Medical School of University of Athens, Ippokrateio

Hospital, Vasilissis Sofias 114, Athens Greece, Pathological Department, Gastroenterology Clinic, Mitera Hospital, Erithrou Stavrou 6, Marousi, Athens, Gastroenterology Clinic, Tzaneio Hospital, I.Afentouli & Zanni, Peiraias Greece, Gastroenterology Clinic, Hospital of Heraklion, Voutes Herakliou, Heraklion, Crete, Gastroenterological Department, Venizeleio Hospital, L. Knosou 44 Heraklion, Crete Greece, Gastroenterological Department, General Hospital of Nikaia, Ikoniou 150, Nikaia, Peiraias, Gastroenterological Clinic, General Hospital “G.Papanikolaou” of Thessaloniki, Exochi Thessalonikis, Exochi Greece, D Pathological Clinic, Ippokrateio Hospital, Konstantinoupoleos 49, Thessaloniki, Gastroenterological Laboratory, Un. General Hospital of Alexandroupolis, Dragana, Alexandroupoli, Kianos Stauros Hospital, Vizyis and Vizantos 1, Thessaloniki Greece, A’ Pathologiki

Clinic, Univ. General Hospital of Alexandroupolis, Dragana, Alexandroupoli, Gastroenterological Department, “G.Gennimatas” Hospital, Mesogeion Av. 154, Athens, Kianos Stauros Hospital, Vizyis and Vizantos 1, Thessaloniki Greece

Contact details

Study institution contact

Athanasios Natsios trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

George Bamias

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/10/2017

Study start date

Planned: 15/10/2018

Actual: 17/10/2018

Data analysis start date
Planned: 19/04/2023

Date of interim report, if expected
Planned: 03/08/2021

Actual: 20/04/2022

Date of final study report
Planned: 19/01/2024

Actual: 14/10/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-4018-clinical-study-protocol-redact.pdf (3.34 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

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 is to assess long term clinical benefit for the biologic naïve patients with inflammatory bowel disease (IBD) on treatment with vedolizumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VEDOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG05) vedolizumab

vedolizumab

Medical condition to be studied

Inflammatory bowel disease

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

200

Study design details

Outcomes

The primary outcome is the drug discontinuation rate in patients with UC or CD under treatment with vedolizumab until 2 years follow-up period. Changes in partial Mayo score(PMS)(UC),Harvey-Bradshaw index(HBI)(CD),short IBD,EQ-5D and treatment satisfaction questionnaire,rate of dose intensification,UC/CD patients on steroids,impact of treat-to-target treatment by PMS(UC)and HBI(CD),endoscopic disease activity,effects of biological parameters,collection of Nr of serious adverse events(AEs),non-serious related AEs,special situation reports.

Data analysis plan

The analysis will be descriptive. All variables will be listed and illustrated by frequency or parameter tables. Continuous variables will be expressed as median, as percent where appropriate, as means (standard deviation SD), and prevalence rates as crude and standardized gender-adjusted, and age-adjusted values. The epidemiological methods will be employed for data analysis and therefore no inferential statistics will be considered with respect to primary and secondary endpoints. Summary statistics for continuous variables will include mean, SD, median and range. For categorical variables the number and percentage of patients in each category will be presented. An interim analysis will be performed when 50 percent (%) of the UC and 50% of the CD enrolled patients will have completed approximately 1 year of follow-up from first patient in (FPI) date, depending in the recruitment rate per group.

Documents

Study results

Vedolizumab-4018-clinical-study-report-redact.pdf (956.67 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, Medical Records, available test results and patient reported outcomes.

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