Retrospective observational study on the effect of vedolizumab treatment on patients with inflammatory bowel disease and extraintestinal manifestations. The EMOTIVE study

First published: 11/10/2018

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47153

EU PAS number

EUPAS25761

Study ID

47153

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Denmark
- [ ] Israel
- [ ] Netherlands
- [ ] Switzerland

Study description

This is retrospective multi-national, multi-centre medical chart review study of patients with inflammatory bowel disease (IBD) and extraintestinal manifestations (EIMs) who have initiated treatment with vedolizumab between 01 January 2015 and 31 December 2016. The study will review the medical charts of patients who have initiated the medical treatment with vedolizumab during the defined eligibility period under standard clinical practice to provide the real-world evidence of treatment effectiveness and safety in the adult patients with ulcerative colitis (UC) or Crohn’s disease (CD) and EIMs. Patients who will be taking vedolizumab as per the standard clinical practice will be observed in this study. The data for participants will be collected in two main periods: Pre-index event period (from the data of diagnosis of UC or CD until one day prior to the date when vedolizumab treatment was initiated during the eligibility period), and Post-index event period (from the date when vedolizumab treatment was initiated during the eligibility period until the death of participants, lost-to-follow up, or date of chart abstraction initiation). The overall duration of the study will be 14 months.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Sheba Medical Center, Meir Medical Center, Tel Aviv Medical Center Israel, Asaf Harofeh medical center, Soroka university medical center, Rambam Medical Center Israel, Zentrum für Gastroenterologie und Hepatologie AG, Centre Hospitalier Universitaire Vaudois Switzerland, University Hospital Zurich, University Hospital Basel, Gastroenterologische Praxis Balsiger, Seibold und Partner Switzerland, LUMC Leiden, Zuyderland ziekenhuis Heerlen, ETZ Netherlands, CHC - Saint Joseph, AZ Groeninge Kortrijk, OLVZ Belgium, Bispebjerg Hospital, Hvidvore University

Hospital Denmark, Hvidvore University Hospital Denmark

Contact details

Study institution contact

Study Lead

Study contact

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Primary lead investigator

Stephan Vavricka

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/06/2017

Actual: 23/06/2017

Study start date

Planned: 01/11/2018

Actual: 08/01/2019

Data analysis start date

Planned: 31/03/2020

Actual: 15/01/2020

Date of final study report
Planned: 30/05/2020

Actual: 08/04/2021

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to describe the percentage of patients treated with vedolizumab experiencing resolution of EIMs within 6 months post-treatment initiation.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective multi-national, multi-centre medical chart review study

Study drug and medical condition

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

VEDOLIZUMAB

Medical condition to be studied

Inflammatory bowel disease

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

The study population consisted of adult patients with IBD and EIMs who initiated treatment with VDZ during the defined Eligibility Period.

Inclusion Criteria:

Patient eligibility was determined according to the following criteria prior to entry into the study:

- The patient diagnosed with moderate to severe UC or CD documented on the medical records
- The patient ≥18 years of age at initiation of VDZ (index date)
- The patient presented, at least, one EIM documented on the medical records at maximum 2 months before VDZ treatment initiation and it had not been resolved by the time of initiation
- The patient received at least one dose of VDZ following standard practice for the treatment of IBD, attended at least one visit after induction and follow-up information was available for at least 6 months after VDZ initiation
- The patient, or when applicable, the patient’s legally acceptable representative signed and dated a written, informed consent form and any

required privacy authorisation prior to the initiation of any study procedures, when required as per local regulations

Exclusion Criteria:
Any patient who met any of the below mentioned criteria did not qualify for entry into the study:
- Index date occurred as part of an interventional clinical trial or patient participated in an interventional clinical trial during the follow-up period
- The patient was diagnosed with indeterminate/an unspecified type of IBD
- The patient initiated VDZ treatment as combination therapy with other biological agents

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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

200

Study design details

Outcomes

Primary outcome measure includes the demographic and clinical characteristics, percentage of patients with resolution of EIMs 6 month's post-treatment initiation with vedolizumab. The secondary outcome includes clinical effectiveness at 14 weeks post induction, Month 6 and 12 post treatment initiation, change in physician assessment, disappearance of inflammatory lesions, change in level of C-reactive protein and faecal calprotectin, percentage of patients with EIMs resolution at Month 12, persistence rate at Month 12, time to treatment discontinuation, and safety events.

Data analysis plan

Continuous variables will be described with number of patients with valid or missing observations, mean, standard deviation (SD), median, 25 and 75 percentiles (P25 and P75 respectively), minimum and maximum.

Documents

Study results

Vedolizumab-5041 CSR Synopsis BV 06Apr2022_Redacted Final.pdf(1.48 MB)

Vedolizumab-5041-Synopsis-08Apr2021.pdf(668.71 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

The source for all collected data will be the patient’s medical records, which include the standard clinical practice in treatment of the patient.

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