Vedolizumab-5056: Clinical Effectiveness of Vedolizumab Used in Frames of Drug Program for Crohn’s Disease Treatment in Poland – Prospective, Observational Study Considering Fatigue and Other Patient-reported-outcomes (PROs) (POLONEZ II)

First published: 28/01/2020

Last updated: 25/06/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44012

EU PAS number

EUPAS32716

Study ID

44012

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This is a multi-centre, non-interventional, and prospective study. This study will review the medical records of patients to evaluate the effectiveness of treatment with vedolizumab in patients with Crohn’s disease (CD), who are administered vedolizumab in Drug program (DP) 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. All participants will be enrolled in one Cohort, where participants will receive vedolizumab as per standard clinical practice and DP requirements at Visit 1 (Week 0), Visit 2 (Week 14), Visit 3 (Week 54), Visit 4 (Week 78), and Visit 5 (Week 102). 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 data collection in this study is approximately 3 years.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Krzysztof Wojciechowski

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Halina Cichoż-Lach

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/11/2019

Actual: 14/11/2019

Study start date

Planned: 07/02/2020

Actual: 03/03/2020

Data analysis start date

Planned: 01/02/2023

Date of interim report, if expected
Planned: 30/04/2021

Date of final study report
Planned: 01/06/2024

Actual: 24/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-5056-clinical-study-protocol-redact.pdf(11.61 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the study is to assess the effectiveness of vedolizumab in CD patients treated in frames of the DP in Poland defined as response and remission rates assessed using CD Activity Index (CDAI).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ENTYVIO

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

VEDOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA) Selective immunosuppressants

Selective immunosuppressants

Medical condition to be studied

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

100

Study design details

Outcomes

The primary outcome will include the percentage of patients achieving response or remission on Week 102. The secondary outcome will include the characteristic of CD patients eligible for DP, Abdominal Pain Score (APS), Number of Liquid or Very Soft Stools (NLVSS), patient reported outcomes (PROs), inflammatory bowel disease-fatique (IBD-F), IBD questionnaire, measurement of quality of life, rate of emergency room visits, hospitalization rate, surgery rate due to CD, and real-world safety of Entyvio.

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. For exploratory analyses of factors influencing response and remission rates a univariate and multivariate logistic regression will be performed. The safety endpoints will be presented as incidence rate calculated using person-time analyses. Appropriate 95 percent (%) confidence interval will be provided.

Documents

Study report

Vedolizumab-5056-clinical-study-report-redact.pdf(1.29 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data will be collected from patients' medical records using electronic case report forms (eCRF).

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