Vedolizumab-5055: Long Term Outcomes of Drug Program for Biological Treatment in Adult Patients With Ulcerative Colitis in Poland (MAZUREK Study)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48425

EU PAS number

EUPAS32684

Study ID

48425

DARWIN EU® study

No

Study countries

Poland

Study description

This is a multicenter, non-interventional study including retrospective data collection with prospective follow-up. This study will assess outcomes of the treatment introduced in the scope of Drug Program (DP) addressed to adult patients with ulcerative colitis (UC) in Poland after biological treatment caseation describing relapse rate in this cohort in consecutive periods. DP is a reimbursement program authorized by Ministry of Health in this country to grant patients access to highly specialized therapies, e.g. biologics, such as VDZ. The study is based on data collection from all patients enrolled to treatment in DP between January 2019 and July 2019. The study will have two cohorts based on the treatment received: Infliximab and vedolizumab. The Investigators will invite eligible patients for Visit 1 for data collection (Week 26 after last dose in DP). Retrospective data will be collected from medical charts of the patients who did not complete the treatment and agreed to participate in the study on Visit 1. Prospective follow-ups will be conducted only for patients who completed treatment in DP with response or remission. Prospective follow-ups with patients will be conducted through patient’s interview and data will be collected using electronic case report forms (eCRFs) on remote Visit 2 (Week 52 after last dose in DP), Visit 3 (Week 78 after last dose in DP), and Visit 4 (Week 104 after last dose in DP). It is planned that 70 patients who completed DP with response/remission will be prospectively followed-up in MAZUREK study, however, total number of enrolled patients will be higher due to fact that data will also be collected from patients who lost response before treatment completion in the DP. The overall duration to collect the data in this study is approximately 2 years and 2 months.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

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Primary lead investigator

Halina Cichoż-Lach

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/10/2019

Actual: 23/10/2019

Study start date

Planned: 07/02/2020

Actual: 02/03/2020

Date of final study report

Planned: 31/10/2024

Actual: 26/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-5055-clinical-study-protocol-redact.pdf(1.49 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:

Disease epidemiology

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective of the study is to assess relapse rate in patients who completed DP with response or remission for UC within Week 26 after biological treatment cessation with infliximab or 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

(L04AA33) vedolizumab

vedolizumab

Medical condition to be studied

Colitis ulcerative

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

70

Study design details

Outcomes

The primary outcome will assess relapse rate after 26 weeks of treatment cessation understood as: any colectomy due to UC, any hospitalization, new course of biological treatment, new course of steroids, necessity to increase a dose of steroids, and new course of an immunomodulator (IMM) (such as azathioprine, 6-mercaptopurine, methotrexate, ciclosporin or tofacitinib) due to exacerbation of UC. Relapse rate in patients who completed DP with response/remission for UC with response within Weeks 52, 78, 104 after treatment cessation with infliximab/vedolizumab, necessity for steroid and biological treatment within Weeks 26, 52, 78, and 104, effectiveness in

induction and maintenance therapy, use of steroids/IMM and real life safety biological treatment in patients with UC in DP.

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. Relapse rates and response rates will be presented with 95 percent (%) confidence intervals. For exploratory analyses of factors influencing response and remission durability groups of patients with relapse reported on each follow-up visit will be compared. In addition, mixed effects models will be performed taking these factors into consideration. The safety endpoints will be presented as incidence rate calculated using person-time analyses.

Documents

Study results

Vedolizumab-5055-clinical-study-report-redact.pdf(1.76 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Data will be collected from patients’ medical records using e-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