Vedolizumab-5060: Association Between Disease Activity and QoL, Fatigue, Mood and Sleep Disorders in Patients with Moderate to Severe Ulcerative Colitis or Crohn’s Disease Treated with Vedolizumab - A Prospective, Observational Study Based on Patient Reported Outcomes (KUJAWIAK)

First published: 15/06/2020

Last updated: 16/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34232

Study ID

103396

DARWIN EU® study

No

Study countries

Poland

Study description

This is an open-label, prospective, non-interventional, national, and multi-center study. This study is designed to document the management and clinical outcome of patients who are eligible for Drug Program (DP) treatment in Poland with ulcerative colitis (UC) and Crohn’s disease (CD) based on real-world data. 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 . The study is based on data collection from all patients enrolled for treatment in DP between September 2020 and March 2022. All patients will be enrolled in one Cohort, where patient will receive vedolizumab intravenous in accordance to Summary of Product Characteristics (SmPC) and DP. Data collection will be scheduled in line with DP visits at Visit 1 (Week 0), Visit 2 (Week 2), Visit 3 (Week 6), and Visit 4 (Week 14). The follow up will be performed after Week 14 in patients who completed the full treatment schedule within DP. The study will enroll approximately 300 patients who initiated treatment with vedolizumab. The study is planned to be conducted in Poland. The overall duration of this study is approximately 25 months.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

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Contact details

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Primary lead investigator

Maria Kłopocka

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/02/2020

Actual: 17/02/2020

Study start date
Planned: 01/09/2020

Actual: 04/09/2020

Data analysis start date
Planned: 30/09/2022

Date of final study report
Planned: 31/08/2023

Actual: 30/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

KUJAWIAK_NIS Protocol_V 2.0_FINAL-amended (V 2.0) updated_Redacted.pdf

(522.55 KB)

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)

Safety study (incl. comparative)

Main study objective:

The primary objective of the study is to determine effect of vedolizumab on quality of life (QoL) measured at Week 14 (end of induction therapy in the DP).

Study Design

Non-interventional study design

Cohort

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

300

Study design details

Outcomes

Primary endpoint will include change from baseline to end of induction therapy in the DP (Week 14) in inflammatory bowel disease questionnaire (IBDQ) total score, domain score (for bowel symptoms, systemic symptoms, emotional function, and social function), and proportion of patients with response (defined as an increase in IBDQ total score of >=16 points at the end of induction therapy in DP). The secondary endpoint will include proportion of patients with

clinical response to vedolizumab treatment at end of induction therapy in DP, change from baseline to end of induction therapy in DP (Week 14) in frequency/severity of fatigue, impact of fatigue on individuals' lives, depression and sleep disturbance expressed as value of T-score calculated from PROMIS Sleep disturbance questionnaire.

Data analysis plan

Standard descriptive statistic methods will be used which comprise the number of patients, arithmetic mean, standard deviation, upper and lower quartiles, minimum, median and maximum. For categorical variables frequencies and percentages (absolute and relative frequencies) will be presented. The safety endpoints will be presented as incidence rate calculated using person-time analyses.

Documents

Study results

Vedolizumab-5060_clinical-study-report-redact.pdf(245.19 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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