A Retrospective Observational Study to describe the Effectiveness and Safety of Vedolizumab With or Without Budesonide Induction Therapy Among Patients with Moderate to Severe Crohn’s Disease (Vedo-BuDy)

First published: 24/04/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42496

EU PAS number

EUPAS28791

Study ID

42496

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Israel
- ☐ Switzerland

Study description

This is a retrospective, multi-national, multi-center medical chart review study of patients diagnosed with moderate to severe Crohn’s disease (CD). This study will review medical records of patients who initiated vedolizumab (VDZ) induction therapy either as VDZ-only or VDZ with budesonide following standard practice, between 01 January 2015 and 31 January 2019 and having a minimum of 14 weeks follow-up. The study will assess the real-world effectiveness and safety, and will describe moderate to severe CD patient profile following induction therapy using VDZ in combination with budesonide and VDZ alone. The data for patients will be collected in two main periods: Pre-index Event Period (Begins on the date of diagnosis of CD), and Post-index Event Period (Begins one day after the Index Date and ends at the earliest of death, lost to follow-up, or 14 weeks after the Index Date). The index period is defined as the date when VDZ induction therapy was initiated. This study will enroll approximately 200 patients. This multi-center study will be conducted in Belgium, Switzerland, and Israel. The overall duration to collect the data in this study is approximately 10 months.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 21 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marc Ferrante

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 30/03/2019

Actual: 11/07/2018

Study start date
Planned: 31/07/2019

Actual: 07/08/2019

Data analysis start date
Planned: 17/08/2020

Actual: 13/08/2020

Date of final study report
Planned: 30/06/2021

Actual: 13/08/2020

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)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the study is to assess the effectiveness in terms of the Crohn’s Disease Activity Index (CDAI) symptoms: abdominal pain (AP) and/or loose stool frequency (LSF) throughout the induction therapy (through week 14) using VDZ with budesonide and VDZ alone among patients with moderate to severe CD.

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

Medical condition to be studied

Crohn's disease

Population studied

Short description of the study population

The study population consisted of adult patients (≥18 years of age) with moderately to severely active CD who were not previously treated with VDZ and had initiated VDZ monotherapy or VDZ in combination with budesonide for at least one week during the defined Eligibility Period between 01 Jan 2015 and 31 Jan 2019. Study patients had active disease at the time of VDZ initiation: reporting at least a moderate AP (AP ≥2) and/or mean daily LSF ≥4 for the previous 7 day

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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

The primary outcomes will assess the mean percentage change in AP and LSF at Week 14 in patients using VDZ with or without budesonide. Mean percentage change in AP and LSF,percentage of patients reaching clinical remission,time to clinical remission at Weeks 2,6,10,and 14, percentage of patients reaching

symptomatic improvement,adverse events, change in levels of C-reactive protein,fecal calprotectin, albumin, haemoglobin and persistence rate at Week 14, time to treatment discontinuation, demographic and clinical characteristics.

Data analysis plan

Data analysis will be mainly descriptive. Continuous variables will be described with number of patients with valid/missing observations, mean, standard deviation (SD), median, 25 and 75 percentiles (P25 and P75, respectively), minimum and maximum. Categorical variables will be described with number of patients with valid/missing observations, number and percentage of patients per response option. Presentation of the descriptive statistics will be stratified by VDZ treatment group (VDZ with budesonide and VDZ-only). A logistic regression model will be used to identify the main factors associated with the decision to prescribe VDZ and budesonide versus VDZ. In the event that a high number of variables show correlation, a penalized logistic regression model (glmnet model) may be used to identify the main factors associated with the decision to prescribe VDZ and budesonide versus VDZ alone. Kaplan-Meier curves will be used for descriptive time-to-event analyses.

Documents

Study results

Vedolizumab-5051_Report Summary_1 Jun 2021.pdf(194.39 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective data collection from patient medical charts: Data will be extracted directly from site electronic medical records (EMRs) where possible and/or abstracted from patient medical records for entry into an electronic data capture (EDC) system.

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