A multi-centre observational study to describe the impact of vedolizumab on concomitant prescribing and quality of life in patients with ulcerative colitis and Crohn’s disease in the UK and Ireland: OCTAVO

First published: 29/04/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS22954

Study ID

42481

DARWIN EU® study

No

Study countries

Ireland

United Kingdom

Study description

This is a part retrospective, part prospective, multi-center, observational study for patients with ulcerative colitis (UC) or Crohn’s disease (CD). The study will review the medical records of patients to provide real-world evidence related to the impact of vedolizumab on corticosteroid, immunomodulator and antibiotic prescribing. In the retrospective cohort, the study will evaluate the extent of corticosteroid prescribing amongst patients with UC initiated on vedolizumab compared with patients initiated on an anti-tumor necrosis factor alpha (anti-TNFα) agent. In a separate prospective cohort, the study will evaluate the impact of vedolizumab on the health related quality of life (HRQoL) of patients with UC or CD during the first 12 months following initiation of vedolizumab. The study will have two cohorts: Cohort 1 and Cohort 2. Patients with UC who received either vedolizumab or an anti-TNF as first-line biologic therapy as part of standard clinical practice in the United Kingdom (UK) will be recruited to Cohort 1. Patients with UC or CD who are being initiated on medical treatment with vedolizumab under standard clinical practice in the UK and Ireland will be recruited to Cohort 2. The overall time to collect patients’ retrospective data related to outcome measures and baseline characteristics in Cohort 1 is approximately 9 months. In Cohort 2, patients will be recruited over 4 months and HRQoL will be collected prospectively, with patient characteristics data to be collected at baseline.

Study status

Finalised

Research institutions and networks

Institutions

St Mark’s Hospital, London North West Healthcare NHS Trust England, Bristol Royal Infirmary, University Hospitals Bristol NHS Foundation Trust England, Manchester Royal Infirmary, Central Manchester University Hospitals NHS Foundation Trust England, Western General Hospital, NHS Lothian England, Mercy University Hospital, Cork (Cohort 2 only) Republic of Ireland

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gareth Parkes

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/03/2017

Actual: 16/03/2017

Study start date
Planned: 29/06/2018

Actual: 10/07/2018

Data analysis start date
Planned: 20/07/2020

Actual: 13/08/2020

Date of final study report
Planned: 23/12/2020

Actual: 18/12/2020

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)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

Primary objective in Cohort 1 is to evaluate changes in corticosteroid prescribing in first 12 months of first-line biologic therapy in UC patients started on vedolizumab compared to patients initiated on an anti-TNF and in Cohort 2 is to evaluate HRQoL, work productivity and activity impairment in first 12 months of vedolizumab therapy started at any point in treatment pathway in UC/CD patients.

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

Inflammatory bowel disease

Population studied

Short description of the study population

Cohort 1

To be included in Cohort 1, patients were required to meet the following criteria:

Inclusion criteria:

- Have a diagnosis of UC.
- Be biologic naïve at the time they were initiated on first-line biologic treatment with VDZ or an anti-TNF as an outpatient.
- Be aged ≥18 years at initiation of first-line biologic treatment with VDZ or anti-TNF.
- Have data available for matching criteria (age, gender, baseline disease extent and corticosteroid use on the day of initiation of first-line biologic treatment with VDZ or an anti-TNF).

- Have at least 12 months of follow-up data after initiation of first-line biologic treatment with VDZ or an anti-TNF.

Exclusion criteria:

- Patients with primary fistulising disease.
- Patients with acute severe disease.
- Patients who were corticosteroid resistant or refractory at the time of initiation of first-line biologic treatment with VDZ or an anti-TNF.
- Patients whose hospital medical records were unavailable for review.
- Patients who declined consent for their primary and secondary care medical records to be accessed for the purposes of this study (except for deceased patients whose data were collected by members of the National Health Service [NHS] direct care team to preserve patient confidentiality).
- Patients enrolled in an interventional clinical trial of an investigational medicinal product during the study period.

Cohort 2

To be included in Cohort 2, patients were required to meet the following criteria:

Inclusion criteria:

- Have a diagnosis of CD or UC.
- Have initiated treatment with VDZ as an outpatient for the first time at the point of enrolment into the study.
- Be aged ≥18 years at initiation of VDZ.

Exclusion criteria:

- Patients with primary fistulising disease.
- Patients with acute severe disease.
- Patients whose hospital medical records were unavailable for review.
- Patients who declined consent for their hospital medical records to be accessed for the purposes of this study.
- Patients enrolled in

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

230

Study design details

Outcomes

Primary outcome for Cohort 1 is mean total dose of corticosteroid in maintenance period of Week 14 to Month 12 in patients started on vedolizumab compared with patients started on anti-TNF as first-line biologic therapy, and for Cohort 2 is change from baseline in mean short inflammatory bowel disease questionnaire (SIBDQ) values at Week 14 and Month 6 and Month 12 after initiation on vedolizumab. Cohort 1 will compare patients initiated on vedolizumab with anti-TNF therapy to assess post-initiation change in biologic treatment, prescribing of corticosteroids, immunomodulators and antibiotics, and type of adverse events related to and caused by vedolizumab or anti-TNF. Cohort 2 will assess change from baseline in patient reported outcomes (PROs) at Week 6 and 14, and at Month 12.

Data analysis plan

Analyses will be descriptive and comparative in nature. Distributions and descriptive statistics of central tendency (arithmetic means or medians) and dispersion (standard deviation or interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies and percentages. Between-group differences for quantitative variables will be evaluated by unpaired t-tests or Wilcoxon rank-sum test. Between-group differences for categorical variables will be assessed by Chi-square test. Within-group differences for quantitative variables will be assessed by paired sample t-test or Wilcoxon matched-pairs signed-ranks test. Within-group differences for categorical variables will be assessed by McNemar test. 95 percent (%) confidence intervals will be presented for estimates of proportions and means of distributions, as appropriate.

Documents

Study results

Vedolizumab-5044 Report Synopsis_24Feb2021.pdf (918.97 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Cohort 1: primary care and secondary care National Health Service (NHS) medical records, Cohort 2: secondary care NHS medical records and online patient questionnaire.

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