Experiences of using vedolizumab in the East Midlands, United Kingdom: A retrospective observational study

First published: 22/05/2018

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23658

Study ID

48537

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This is a retrospective, observational study to investigate the use of vedolizumab and treatment outcomes in patients with inflammatory bowel disease (IBD) in the East Midlands. This study will utilize patient-level data in the East Midlands. Approximately 200 patients with IBD will be included in this study. Patients who were initiated on vedolizumab treatment between 1st November 2014 and 30th November 2016 will be followed up to the earliest of the following dates: last follow-up, date of death (if applicable) or 31st March 2017.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

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Institution

Nottingham University Hospitals NHS Trust United Kingdom, Chesterfield Royal Hospital NHS Foundation Trust United Kingdom, Derby Teaching

Hospitals NHS Foundation Trust United Kingdom, Kettering General Hospital NHS Foundation Trust United Kingdom, Sherwood Forest Hospitals NHS Foundation Trust United Kingdom, United Lincolnshire Hospitals NHS Trust United Kingdom, University Hospitals of Leicester NHS Trust United Kingdom

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gordon Moran

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/10/2017

Actual: 25/10/2017

Study start date
Planned: 21/05/2018

Actual: 01/06/2018

Data analysis start date
Planned: 04/06/2018

Actual: 31/07/2018

Date of final study report
Planned: 31/08/2018

Actual: 31/07/2019

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 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:

Secondary use of data

Main study objective:

The main objective of the study is to describe corticosteroid-free and clinical remission in patients with IBD after initiation on vedolizumab.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective observational study

Study drug and medical condition

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

VEDOLIZUMAB

Medical condition to be studied

Inflammatory bowel disease

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with inflammatory bowel disease (IBD) receiving vedolizumab between 1st November 2014 and 30th November 2016 in the East Midlands.

Inclusion criteria:

• Patients aged ≥18 years at initiation of vedolizumab.

• Patients with clinically confirmed diagnosis of Crohn’s disease (CD), ulcerative colitis (UC), or IBD of unclassified type (IBDU), as recorded in medical records.

• Patients who received their first dose of vedolizumab between 1st November 2014 and 30th November 2016 in one of the participating study centres.

Exclusion criteria:

• Patients whose hospital medical records were unavailable for review.

• Patients enrolled in an interventional clinical trial of an investigational medicinal product during the observation period.

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

Other

Special population of interest, other

Patients with inflammatory bowel disease, colitis ulcerative, crohn's disease

Estimated number of subjects

200

Study design details

Outcomes

The primary outcome in this study is time to corticosteroid-free remission after initiation on vedolizumab. Time to clinical remission, change in disease activity from baseline, concomitant drug use, mucosal damage and healing, time to follow up endoscopy, rate of surgery, rate of admissions and adverse events.

Data analysis plan

Both distributions and descriptive statistics of central tendency (medians and arithmetic means) and dispersion (interquartile range and standard deviation) will be presented for quantitative variables wherever possible. Nominal variables will be described with frequencies and percentages. Confidence intervals will be provided for means of numeric variables.

Documents

Study results

Vedolizumab-5049 - Synopsis - _FINAL_V1 1_31JUL2019.pdf(711.73 KB)

Vedolizumab-5049_Synopsis_Redacted.pdf(794.32 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

Patient-level data from medical records already collected by each study centre.

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