Vedolizumab-5028: A Retrospective UK Chart Review of Early Vedolizumab (Entyvio®) Experience: Real World Treatment, Effectiveness and Safety in Inflammatory Bowel Disease (IBD)

First published: 11/03/2016

Last updated: 21/11/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44112

EU PAS number

EUPAS12537

Study ID

44112

DARWIN EU® study

No

Study countries

United Kingdom

Study description

This is retrospective, observational, multi-center study of patients with ulcerative colitis (UC) and Crohn's disease (CD), will be conducted based on the secondary data derived from patients medical records and hospital databases. Patients who meet the eligibility criteria will be selected from a total of 6 NHS study across the United Kingdom. Patients who were on vedolizumab treatment initiated 10 to 14 weeks prior to start of data collection in order to allow adequate time to observe the response to treatment. Treatment response will be assessed at Week 10 and Week 14 for patients with UC and CD respectively. The study is aimed to evaluate the effectiveness, patterns of use and tolerability of vedolizumab in real world treatment.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

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Institution

Multiple centres: 6 centres are involved in the study

Networks

pH Associates

Contact details

Study institution contact

Fraser Cummings

Study contact

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Primary lead investigator

Fraser Cummings

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/02/2016

Actual: 16/09/2015

Study start date
Planned: 07/03/2016

Actual: 22/04/2016

Date of final study report
Planned: 31/05/2016

Actual: 14/11/2017

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:

Secondary use of data

Main study objective:

The primary objective of this study is to describe the early real world use of vedolizumab in the treatment of UC and CD.

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

Crohn's disease

Population studied

Short description of the study population

Patients with ulcerative colitis (UC) and Crohn's disease (CD) who were on vedolizumab treatment initiated 10 to 14 weeks prior to start of data collection were selected from a total of 6 NHS study across the United Kingdom.

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 Crohn's disease, Colitis ulcerative

Estimated number of subjects

200

Study design details

Outcomes

Primary outcome measure will assess the median time upon treatment with vedolizumab. The secondary outcome will assess effectiveness, safety, tolerability and patient characteristics upon treatment of vedolizumab. Previous treatment history of patients will also be evaluated.

Data analysis plan

Descriptive statistical analyses are planned to be reported due to the retrospective observational nature of the study. Kaplan-Meier curve will be used to report the primary outcome measure.

Documents

Study publications

https://pubmed.ncbi.nlm.nih.gov/30817598/

Data management

Data sources

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Laboratory data, Investigation reports

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