Vedolizumab-5014: Incidence of adverse events of special interest in patients with Crohn’s disease or ulcerative colitis treated with Entyvio as compared to anti-TNF-alpha agents

First published: 09/02/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14135

Study ID

44109

DARWIN EU® study

No

Study countries

☐ United States

Study description

Study was withdrawn prior to data collection - The drug being tested in this study is called Entyvio (vedolizumab). Vedolizumab was launched in the United States in June 2014 for treatment of people who have crohn's disease (CD) and ulcerative colitis (UC). This study will look at the real-world evidence on utilization and safety of Entyvio in routine clinical practice. The study will enroll approximately 1250 participants. The data will be taken from the Optum health insurance claims database from May 1, 2000. All participants who received one of the two treatments where included in this study: - Vedolizumab infusion - Anti-tumor necrosis factor-alpha (TNF-alpha) agent The overall time to extract the data from the Optum claims database is approximately 4 years. Participants in both groups will be followed from index date to the occurrence of last data collected, disenrollment of membership, switching to another biologic product, or date of death, whichever date comes first.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Contact details

Study institution contact

Huifang Liang trialdisclosures@takeda.com

Study contact

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Primary lead investigator

Huifang Liang

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/09/2015

Actual: 11/09/2015

Study start date

Planned: 30/11/2015

Actual: 30/11/2015

Data analysis start date

Planned: 30/11/2015

Actual: 30/11/2015

Date of final study report

Planned: 01/06/2020

Actual: 30/11/2015

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe clinical characteristics and treatment history of participants initiating Entyvio and to quantify the incidence rates of adverse events in UC or CD participants who initiated Entyvio or an anti-TNF-alpha agent.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

VEDOLIZUMAB

ADALIMUMAB

CERTOLIZUMAB

GOLIMUMAB

INFLIXIMAB

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

All participants with UC or CD who initiated Entyvio (Vedolizumab infusion) or an anti-TNF-alpha agent as first line or second line biologic therapy on or after 1 June 2014. Data was collected from Optum health insurance claims database from May 1, 2000.

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

1250

Study design details

Outcomes

Percentage of Participants with Adverse Events of Special Interest

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Data analysis plan

Descriptive analysis used to describe clinical characteristics and treatment history of participants. Incidence rates (and 95 percent % confidence interval CIs) of outcomes will be calculated as cumulative incidence and as incidence rate per 100 person years. Rates will be stratified into Entyvio or anti-TNF-alpha agent initiated as 1st or 2nd line biologic therapy. Mean and standard deviations, medians and ranges will be generated for continuous variables. Participant counts, proportions and Chi-square test will be used for categorical variables. For continuous variables, Student's t test will be used to test means between groups (CD vs UC, Entyvio vs anti-TNF-alpha), and Rank sums Wilcoxon two-sample median test will be used to test medians between groups. Two-sample independent tests will be used for group comparisons, participants who had both Entyvio and anti-TNF-alpha observation periods will be considered Entyvio participants only for baseline characteristics.

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)

Administrative healthcare records (e.g., claims)

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