Safety and Effectiveness of Vedolizumab IV in Real World Clinical Practice in Taiwan: A Registry-Based Study

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Study Finalised

Administrative details

EU PAS number

EUPAS27544

Study ID

46956

DARWIN EU® study

No

Study countries

Taiwan

Study description

This is a prospective longitudinal cohort study of patients with ulcerative colitis (UC) and Crohn’s disease (CD) who receive at least one dose of vedolizumab intravenous (IV) from August 2017 through May 2020. The study will analyze data from the Taiwan Society of Inflammatory Bowel Disease (TSIBD) prospective inflammatory bowel disease (IBD) registry to provide real-world data on the safety and effectiveness of vedolizumab IV in Taiwanese patients. The Registry collects disease baseline information on patient upon first IBD diagnoses and clinical details on each quarterly follow-up visits. For the purpose of this study, patient demographics, clinical characteristics, and treatment history will be collected on the index date (t0) which is the date a patient receives first dose of vedolizumab IV. The Registry is prospectively updated every 3 months by participating IBD clinics with new information on patient’s disease type, locations, and severity, in addition, information is recorded on changes to medications, IBD-related surgeries and hospitalizations, and reasons for vedolizumab discontinuation (when applicable). This study will enroll at least 90 patients. The overall duration to collect data in this study is 2.75 years.

Study status

Finalised

Research institutions and networks

Institutions

Changhua Christian Hospital, Cheng Hsin General Hospital, Chi Mei Medical Center, Yongkang Taiwan, China Medical University Hospital, Chung

Shan Medical University Hospital, Chung-Ho Memorial Hospital Taiwan, E-Da Hospital, Far Eastern Memorial Hospital, Hualien Tzu Chi Medical Center Taiwan, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung Veterans General Hospital, Linkou Chang Gung Memorial Hospital Taiwan, Mackay Memorial Hospital, Mennonite Christian Hospital, National Cheng Kung University Hospital Taiwan, National Taiwan University Hospital, Shin Kong Wu Ho-Su Memorial Hospital, Taichung Veterans General Hospital Taiwan, Taipei City Hospital Taiwan, Taipei Veterans General Hospital Taiwan, Tri-Service General Hospital Taiwan

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shuchen Wei

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/11/2016

Actual: 17/11/2016

Study start date

Planned: 01/08/2017

Actual: 01/08/2017

Data analysis start date

Planned: 15/06/2020

Actual: 17/05/2020

Date of final study report

Planned: 26/10/2020

Actual: 06/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-5026-Protocol_V2_Redacted.pdf (1.67 MB)

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:

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 safety and effectiveness of vedolizumab IV in patients with UC and CD in Taiwan.

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

Inflammatory bowel disease

Crohn's disease

Colitis ulcerative

Population studied

Short description of the study population

The study population is all UC and CD patients in the Registry who receive at least 1 dose of vedolizumab IV during a 2.75-year period (ie, from August 2017 through 17 May 2020).

Inclusion and Exclusion Criteria
The following inclusion criteria will be used to identify patients treated with vedolizumab IV in the Registry:
 Patient initiated vedolizumab IV treatment from August 2017 through 17 May 2020.
 Patient was enrolled in the Registry.
 Patient was at least 18 years of age at time of initiating vedolizumab IV.
 IBD clinic and local institutional review board (IRB) (where required) agrees to use of their data from the Registry in this analysis.
The following exclusion criteria will be applied:
 Patient was enrolled in an IBD clinical trial at time of using vedolizumab IV.

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

Ulcerative colitis (UC) and Crohn’s disease (CD) patients

Estimated number of subjects

Study design details

Outcomes

The primary outcomes include treatment persistence for effectiveness assessment and incidence rates of adverse events for safety assessment.

Data analysis plan

The analytical dataset will be comprised of all patients in the Registry who receive at least 1 dose of vedolizumab IV from August 2017 through 17 May 2020. Longitudinal data on each patient will be abstracted from the registry and form the analytical dataset. Continuous variables will be summarized using: number of patients (N), mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum, where appropriate. Categorical variables will be summarized using the number of patients (N) and percentage of patients for each category where appropriate. There will not be imputation of missing data.

Documents

Study results

Vedolizumab-5026_RDS_26Apr2022.pdf (940.7 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)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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