Vedolizumab-4030: Understand the Outcomes of Inflammatory Bowel Disease (IBD) Patients Treated with Biologics in Taiwan – A Decentralized Vedolizumab and Biologic Agents Core Assessments in IBD Collaboration

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Study Finalised

Administrative details

EU PAS number

EUPAS48289

Study ID

50648

DARWIN EU® study

No

Study countries

Taiwan

Study status

Finalised

Research institutions and networks

Institutions

Takeda

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Institution

Chang Gung Medical Foundation, Linkou Taoyuan City, China Medical University Hospital Taichung City, National Taiwan University Hospital Taipei, Taichung Veterans General Hospital Taichung City

Contact details

Study institution contact

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Primary lead investigator

Study Lead

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/03/2020

Actual: 03/03/2020

Study start date

Planned: 27/05/2021

Actual: 27/05/2021

Date of final study report

Planned: 31/03/2023

Actual: 08/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Vedolizumab-4030_Protocol_Redacted.pdf (1.75 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to quantify the relapse rate after biologic discontinuation, and identify predictors of relapse. Additionally, treatment safety and effectiveness of biologics including anti-TNF-α and vedolizumab in IBD patients will be quantified, along with predictors of response to treatment.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective 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

Crohn's disease

Colitis ulcerative

Population studied

Short description of the study population

Newly diagnosed inflammatory bowel disease (IBD) patients aged 20 years or older treated with biologics including vedolizumab, adalimumab, infliximab, or golimumab during February 2008 to March 2020.

Inclusion Criteria:

1. Patient aged ≥ 20 years old when IBD (CD or UC) was first diagnosed during February 2008 to March 2020 (or per local IRB permitted date).

- CD (ICD-9-CM: 555.X or ICD-10-CM: K50.XX, K50.XXX)
- UC (ICD-9-CM: 556.X or ICD-10-CM: K51.XX, K51.XXX)

2. Had received any dose of biologics for IBD treatment, including vedolizumab adalimumab, infliximab or golimumab, from February 2008 to March 2020 (or per local IRB permitted date)

Exclusion Criteria:

Patients with any suspected diagnosis of CD or UC within one year before the initial date of confirmed IBD diagnosis will be excluded.

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

Inflammatory bowel disease patients

Estimated number of subjects

724

Study design details

Outcomes

% of relapse and time-to-relapse and correlation b/t clinical variables and the relapse post biologics discontinuation. Incidence rates and potential correlation b/t clinical variables of patients achieving treatment effectiveness and incidence rates of opportunistic, hepatic, GI, respiratory infection/failure or sepsis/septic shock among patients receiving vedolizumab vs those receiving anti-TNF.

Data analysis plan

All demographic covariates will be summarized by the types of disease (CD or UC) and by the types of biologics (anti-TNF-α or anti-α4β7 integrin) descriptively. Categorical variables will be presented as counts and percentage and will be analyzed by Chi-square test. Continuous variables will be presented as number of observation (n), mean and median, standard deviation, minimum and maximum and will be analyzed by Student’s t-test. The predictors will be analyzed using time dependent Cox regression model. All statistical significance will be set at $p < 0.05$ unless otherwise specified.

Documents

Study results

Vedolizumab-4030-Clinical-Study-Report-Redact.pdf (719.28 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 source(s), other

Chang Gung Research Database (CGRD) Taiwan, China Medical University Hospital (CMUH)-Clinical Research Database Taiwan, National Taiwan University Hospital-integrated Medical database (NTUH-iMD) Taiwan, Taichung Veterans General Hospital (TVGH)-Research Database Taiwan

Data sources (types)

Electronic healthcare records (EHR)

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