ENTYVIO® Outcomes in Real-world, Bio-naïve Ulcerative Colitis and Crohn’s Disease Patients (EVOLVE)—Greece (EVOLVE-Greece)

First published: 19/07/2017

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS19669

Study ID

36412

DARWIN EU® study

No

Study countries

☐ Greece

Study description

The study aims to evaluate long-term (>6 months) real-world treatment patterns, clinical effectiveness and safety of vedolizumab (VDZ) in biologic-naïve ulcerative colitis (UC) and Crohn’s disease (CD) patients in Greece.

Study status

Finalised

Research institutions and networks

Institutions

Evaggelismos Hospital

General Hospital of Nikaia Nikaia, Venizeleio Hospital Crete, University Hospital Crete, Erythros Stavros Athens, Patra Rio University Hospital Agrinio, Euroclinic Athens, Laiko Hospital Athens, Alexandra Hospital Athina, Iatriko Athinon Marousi Athens, Erythros Stavros Athens

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Demuth Dirk

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/05/2017

Study start date

Planned: 21/05/2018

Actual: 24/05/2018

Data analysis start date

Planned: 31/01/2019

Actual: 28/02/2019

Date of final study report

Planned: 28/02/2019

Actual: 29/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Development Centre Europe Ltd

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

VDZ-5036

Methodological aspects

Study type

Study type list

Study topic:

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:

1. Describe treatment patterns associated with first-line VDZ use (i.e. biologic-naïve patients)2. Describe the real-world clinical effectiveness of first-line VDZ at least six months post-treatment initiation

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Inflammatory bowel disease

Population studied

Short description of the study population

Patients who were diagnosed with ulcerative colitis (UC) or Crohn’s disease (CD) and who initiated first-line biologic treatment with Vedolizumab (VDZ).

Only patients who initiated VDZ and were biologic-naïve at the point of VDZ initiation (index event) were included in the study. Local site staff identified the sampling frame of patients UC or CD who initiated first-line biologic therapy with VDZ during the eligibility period.
Inclusion criteria: Medical chart documentation of UC or CD diagnosis; at least one dose of VDZ during the eligibility period (1 September 2015 to date of site initiation [first site initiated: 8 May 2018; last site initiated: 6 August 2018]); aged ≥18 years at the time of VDZ treatment initiation (index event); biologic-naïve (no prior biologic use for any pathology including IBD) at time of index event; minimum of six months duration between date of index event and date of chart abstraction initiation.
Exclusion criteria: Received VDZ as part of an interventional clinical trial (includes index treatment); initiated index treatment as combination therapy with two biologic agents; empty or missing medical record; part or all of patient's index treatment was received at a different site, and the patient's medical record pertaining to this care was not accessible.

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

Immunocompromised

Estimated number of subjects

100

Study design details

Outcomes

Changes in patients' biologic treatment (6 mths) following initiation of the index treatment will be described (e.g. treatment persistence, dose modifications, concomitant treatments, discontinuation). Clinical effectiveness will be defined by changes in disease measures and outcomes from the diagnostic procedures conducted closest to the date of index event, and all assessments during post-index, - Disease characteristics- Clinical effectiveness at least 12 months post-treatment initiation- Safety- Healthcare resource utilisation

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Data analysis plan

A statistical analysis plan (SAP) will be developed prior to any data analyses being performed that defines all analytic populations and sub-populations, time since diagnosis to index event, including definition of derived variables such as treatment response and clinical effectiveness. The SAP will further provide a detailed description of analyses to be performed, and describe methods to deal with unknown data and censoring.Results will be reported in a descriptive manner, as follows:• Continuous data will be described by their mean, median, standard deviation (SD), minimum, and maximum. • Categorical variables will be described by frequency and percentages (n, %).• Kaplan-Meier curves will be presented to describe time-to-event analyses (e.g. time to first dose escalation, time to discontinuation).• Univariate/multivariate logistic regression will be used to analyse potential predictors of and/or variables associated with response to first-line VDZ Tx

Documents

Study results

Vedolizumab-5036 - Takeda EVOLVE_redacted.pdf(145.72 KB)

Data management

ENCePP Seal

Conflicts of interest of investigators

GJM CoI.pdf(10.87 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Retrospective data collection from the patients' medical records

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

Unknown