A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA® (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

First published: 11/10/2017

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS21010

Study ID

48639

DARWIN EU® study

No

Study countries

Australia

Austria

Belgium
Canada
Croatia
Denmark
France
Germany
Greece
Ireland
Israel
Italy
Mexico
Netherlands
New Zealand
Norway
Puerto Rico
Spain
Sweden
United Kingdom
United States

Study description

This is a registry study to evaluate the long-term safety and effectiveness of adalimumab in adult patients with moderately to severely active UC who are treated as recommended in the product label.

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2011

Actual: 01/01/2011

Study start date

Planned: 29/04/2013

Actual: 29/04/2013

Date of final study report

Planned: 25/05/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p11282 synopsis.pdf (96.74 KB)

p11282-protocol-amendment4-synopsis.pdf (102.35 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

P11-282

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The primary objective of this study is to evaluate the long-term safety of HUMIRA® in moderately to severely active UC adult patients (18 years of age or older) who are treated per routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ADALIMUMAB

Medical condition to be studied

Colitis ulcerative

Population studied

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)

Estimated number of subjects

5450

Study design details

Outcomes

Number and percent of patients experiencing serious adverse events (SAEs) and adverse events of interest (AEIs), - Safety reporting forms will be used to estimate health care resource utilization - Partial Mayo Score - CRP, hemoglobin and fecal calprotectin values - Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ) - Work Productivity and Activity Impairment (WPAI) - Treatment Satisfaction Questionnaire for Medication (TSQM) - EQ-5D-5L

Data analysis plan

For demographics/baseline, medical history, previous/concomitant medication and effectiveness data, categorical variables will be summarized using frequencies and percentages. Continuous variables will be summarized using descriptive statistics by the number of non-missing observations, mean, standard deviation, 1st quartile, median, 3rd quartile, minimum and maximum. In addition for effectiveness data, 95% CI for the mean will be provided. For safety data, treatment-emergent (TE) and observational adverse events (AEs) will be coded using the most current version of the Medical Dictionary for Regulatory Activities (MedDRA). The number and percent of patients

experiencing TE and observational AEs will be summarized as well as tabulated by system organ class (SOC) and MedDRA preferred term (PT). The number of AEs per 100 patient-years will be summarized. In addition, by-patient listings will be provided for TE and observational AEs.

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

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