A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA (adalimumab) in Pediatric Patients with Moderately to Severely Active Crohn’s Disease (CD) - CAPE

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Study Ongoing

Administrative details

EU PAS number

EUPAS6213

Study ID

48820

DARWIN EU® study

No

Study countries

Bosnia and Herzegovina

Bulgaria

Canada
Croatia
Czechia
Denmark
Estonia
France
Germany
Greece
Ireland
Israel
Italy
Lithuania
Netherlands
Portugal
Puerto Rico
Romania
Spain
Sweden
United Kingdom
United States

Study description

This is a registry study to evaluate the long-term safety and effectiveness of adalimumab in pediatric patients with moderately to severely active CD 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: 01/01/2012

Actual: 01/01/2012

Study start date

Planned: 28/07/2014

Actual: 28/08/2014

Date of final study report

Planned: 31/10/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p11292-protocol-pmos-abstract-eupas register.pdf (157.15 KB)

p11292-protocol-pmos-amendment1-abstract.pdf (191.65 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

P11-292

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)

Main study objective:

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

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

HUMIRA

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

ADALIMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AB04) adalimumab

adalimumab

Medical condition to be studied

Crohn's disease

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

1.434

Study design details

Outcomes

-Number (No.) and percentage of subjects with SAEs-No. and percentage of subjects with AESI of infections, malignancies, and pregnancies
-No. and percentage of subjects with other AESI-No. of treatment-emergent SAEs per 100 patient years (PYs)
-No. of treatment-emergent AESI per 100 PYs of infections, malignancies
-No. of treatment-emergent other AESI per 100 PYs,
-Short Pediatric Crohn's Disease Activity Index (sh-PCDAI)-Physician's Global Assessment of Disease Activity (PGA)-IMPACT III-Short Quality of Life in Inflammatory Bowel Disease Questionnaire (SIBDQ)-Work Productivity and

Data analysis plan

For effectiveness data, continuous variables will be summarized using descriptive statistics by the number of non-missing observations, mean, 95% CI for mean, standard deviation, 1st quartile, median, 3rd quartile, minimum, and maximum.

Categorical variables will be summarized using frequencies and percentages.

For safety data, treatment-emergent 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 serious AEs and AEs of interest will be tabulated by system organ class (SOC) and MedDRA preferred term (PT).

Events per 100 patient-years, i.e. the number of treatment-emergent serious adverse events (SAEs) and adverse events of special interest (AESI) per 100 patient-years, will be tabulated.

Complete, specific details of the statistical analysis will be described and fully documented in the Statistical Analysis Plan (SAP).

Data management

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