A Long-term, Multi-center, Longitudinal Post-marketing, Observational Study to Assess Long Term Safety and Effectiveness of HUMIRA® (Adalimumab) in Children With Moderately to Severely Active Polyarticular or Polyarticular-course Juvenile Idiopathic Arthritis (JIA) (STRIVE)

First published: 07/08/2019

Last updated: 24/03/2025

Study Finalised

Administrative details

EU PAS number

EUPAS30576

Study ID

48817

DARWIN EU® study

No

Study countries

Australia
Austria
Czechia
Denmark
France
Germany
Greece
Hungary
Italy
Netherlands
Norway
Portugal
Puerto Rico
Slovakia
Spain
Sweden
United States

Study description

This is a global registry, to evaluate the long-term safety of Humira® in patients with moderate to severe polyarticular Juvenile Idiopathic Arthritis (JIA), that are treated as recommended in the Humira® product label. Patients treated with MTX will be considered a reference group. Patients will be followed in both the Humira® and Methotrexate (MTX) arms for 10 years from the enrollment date into one of the treatment arms.

Study status

Finalised

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

Actual: 19/08/2008

Study start date

Actual: 11/07/2008

Date of final study report

Actual: 27/06/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p10262-protocol-amendment6_Redacted_05Aug2019.pdf (2.93 MB)

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

P10-262

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this study is to evaluate the long term safety of Humira in patients with moderately to severely active polyarticular or polyarticular-course JIA who are prescribed and treated in accordance with the approved local Humira product label under the conditions of a routine clinical setting.

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

Juvenile idiopathic arthritis

Population studied

Age groups

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

Estimated number of subjects

849

Study design details

Outcomes

-Incidence of Serious Adverse Events (SAEs)-Incidence of Adverse Events (AEs) of Interest, -Pediatric American College of Rheumatology (PedACR) 50-PedACR 70-PedACR 30-Child Health Questionnaire (CHQ-PF50)-PedACR 90-Juvenile arthritis disease activity score (JADAS)-Physical function of Disability Index of Childhood Health Assessment Questionnaire

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Data analysis plan

The number and percent of patients experiencing SAEs and AEs of special interest during the registry, regardless of whether the AEs are reported during or after Humira or MTX treatment, will be tabulated by body system and Medical Dictionary for Drug Regulatory Activities (MedDRA) preferred term. Rates (event per 100 patient year of observation) of SAEs and AEs of Special Interest and 95% confidence interval will be provided.

Documents

Study results

P10-262-pmos-results-rpt-Abstract_Redacted.pdf (162.92 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

Spontaneous reporting system, Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown