OBSERVATIONAL SAFETY AND EFFECTIVENESS STUDY OF PATIENTS WITH POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS TREATED WITH TOCILIZUMAB

First published: 07/08/2015

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Study Ongoing

Administrative details

EU PAS number

EUPAS10547

Study ID

49484

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United States

Study description

This protocol describes the collection, analysis, and reporting of aggregate data from the feeder registries to examine the long-term safety and effectiveness profile of Tocilizumab (TCZ) in patients with Polyarticular juvenile idiopathic arthritis (pJIA) in an observational setting.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lutaf Islam

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/11/2014

Study start date

Planned: 14/08/2015

Actual: 15/06/2015

Data analysis start date
Planned: 31/12/2025

Date of final study report
Planned: 30/06/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd.

Study protocol

Prot WA29358 (pJIA Registry) tocilizumab_Redacted.pdf (1.02 MB)

Prot WA29358 (pJIA Registry) tocilizumab v7, Published Output-1_Redacted.pdf (680.12 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

WA29358

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

Safety study (incl. comparative)

If ‘other’, further details on the scope of the study

Observational safety and effectiveness study as post-marketing commitment to FDA and EMA

Data collection methods:

Secondary use of data

Study design:

This is an international, multicenter, prospective, observational-cohort study to examine long-term safety and effectiveness data from patients with pJIA.

Main study objective:

To assess the long-term safety and effectiveness of TCZ in relation to comparator biologics in the treatment of pJIA in a real-world setting for 5 years.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ROACTEMRA

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

TOCILIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC07) tocilizumab

tocilizumab

Medical condition to be studied

Juvenile idiopathic arthritis

Additional medical condition(s)

Polyarticular juvenile idiopathic arthritis

Population studied

Short description of the study population

Patients enrolled in the feeder registries must meet all of the following criteria for
inclusion in this study:
- Diagnosis of pJIA, defined according to ILAR classification (Petty et al. 2004), and in line with the licensed indications in the United States and the European Union:
Patients with RF-positive pJIA
Patients with RF-negative pJIA
Patients with eoJIA
- Initiation of treatment with TCZ (IV or SC) or a comparator biologic. The TCZ group will include patients with no previous exposure to TCZ (IV or SC). The comparator biologic group will include patients with no previous exposure to that specific comparator biologic.
- Age <=17 years at the time of initiation of treatment with TCZ (IV or SC) or a comparator biologic

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Age groups

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

Estimated number of subjects

600

Study design details

Comparators

Patients receiving a comparator biologic

Outcomes

- Rate of serious adverse events
- Rates of serious adverse events in the following categories of special interest: * Infections * Cardiovascular events * Malignancies * Gastrointestinal perforations
- Rate and treatment outcome of uveitis - Growth patterns - Development patterns
- Juvenile Arthritis Disease Activity Score in 10 joints (JADAS-10)

Data analysis plan

Descriptive summary analyses will be used to characterize baseline demographics, medical history, medications, growth and development. Incidence rates, with 95% confidence intervals, will be provided for serious adverse events. Height standard deviation scores will be summarized descriptively over time by treatment group. The data for development patterns will be summarized by gender for each treatment group.
The rate of uveitis and description of treatment outcome will be summarized. JADAS-10 will be summarized over time.

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

Childhood Arthritis and Rheumatology Research Alliance (CARRA) registry, Juvenile arthritis Methotrexate/Biologics long-term Observation (JuMBO) registry, and Biologika in der Kinderrheumatologie-Register (Biologics in Pediatric
Rheumatology Registry) (BiKeR)

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection

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