An Observational Study to Assess the Utilisation and Safety of Ixekizumab Among Pediatric Patients Treated in the Course of Routine Clinical Care (I1F-MC-B015)

First published: 11/06/2021

Last updated: 07/01/2026

Study Planned

Administrative details

EU PAS number

EUPAS36306

Study ID

36307

DARWIN EU® study

No

Study countries

☐ United States

Study status

Planned

Research institutions and networks

Institutions

HealthCore

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Institution

Contact details

Study institution contact

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Study contact

carragher_natacha@lilly.com

Primary lead investigator

Natacha Carragher

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2020

Actual: 25/08/2020

Study start date

Planned: 31/08/2021

Date of final study report
Planned: 30/04/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Co.

Study protocol

I1F-MC-B015 PASS Protocol v1.0_Redacted.pdf (4.36 MB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Study design:

This cohort study uses US administrative health care data from the HealthCore Integrated Research Database (HIRD). It will take place in two phases as described below. Phase 1: Uptake Monitoring. Phase 2: Comparative Safety Analysis.

Main study objective:

To monitor the uptake of ixekizumab in a real-world pediatric population To characterize the demographics and clinical characteristics of pediatric patients receiving ixekizumab To provide additional information about the long-term safety pertaining to serious infections and inflammatory bowel disease

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IXEKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC13) ixekizumab

ixekizumab

Medical condition to be studied

Psoriasis

Infection

Colitis ulcerative

Crohn's disease

Population studied

Short description of the study population

children (6 to less than 18 years of age) within a large, US administrative insurance claims database diagnosed with plaque psoriasis and exposed to ixekizumab or comparator medications

Age groups

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

Estimated number of subjects

400

Study design details

Comparators

Comparator medications: biologic medication (etanercept), non-biologic systemic
medication (acitretin, cyclosporine, and methotrexate), and non-systemic topical treatment
(corticosteroids, calcipotriene).

Outcomes

Demographic and clinical characteristics of pediatric patients receiving ixekizumab, Long-term safety pertaining to serious infections and inflammatory bowel disease in pediatric patients receiving ixekizumab

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Data analysis plan

TBD

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)

Administrative healthcare records (e.g., claims)

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