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)

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Last updated: 22/04/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36307

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

Elsie Grace

Study contact

elgrace@lilly.com

Primary lead investigator

Elsie Grace

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

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

Medical condition to be studied

Psoriasis

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

400

Study design details

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

Data analysis plan

TBD

Data management

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