A Prospective, Observational Study to Assess the Long-Term Safety of Ixekizumab Compared with Other Therapies Used in the Treatment of Adults with Moderate-to-Severe Psoriasis in the Course of Routine Clinical Care (I1F-MC-RHBT)

First published: 24/10/2018

Last updated: 07/01/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS18132

Study ID

32737

DARWIN EU® study

No

Study countries

Canada

United States

Study status

Ongoing

Research institutions and networks

Institutions

Corrona Rheumatoid Arthritis Registry

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Natacha Carragher

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 15/07/2015

Study start date
Actual: 20/04/2016

Date of final study report
Planned: 31/05/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

RHBT 05 Protocol(b)_Redacted.pdf (3.72 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This study uses prospectively collected data from the Corrona Psoriasis Registry, an existing prospective, multicentre, observational psoriasis registry, and will use a cohort study design.

Main study objective:

To assess the long-term safety of ixekizumab compared with other therapies used in the treatment of adults with moderate-to-severe psoriasis (may include psoriatic arthritis) in the course of routine clinical care

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

Population studied

Short description of the study population

The study population includes all patients in the Corrona Psoriasis Registry, with some exclusions employed for specific analyses.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

4000

Study design details

Comparators

A minimum of 4000 non-IL-17 comparator patients

Outcomes

Malignancy, excluding non-melanoma skin cancer, Non-melanoma skin cancer, serious infections, opportunistic infections (including tuberculosis), inflammatory bowel disease, major adverse cardiac events, serious hypersensitivity reactions, demyelinating disease, and gastrointestinal perforation

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Data analysis plan

A number of descriptive statistics and crude rates will be generated to understand the registry data before comparative analyses begin. Propensity score models will be used to account for channeling bias. The models will include variables that are known risk factors for safety outcomes and associated with systemic treatments for psoriasis. Before initiating the outcome analysis, the ability of the propensity score stratification to balance the distribution of baseline confounders and reduce channeling bias will be evaluated. Cox proportional hazards models will be used to evaluate the rate of study outcomes among ixekizumab treated patients relative to the comparator populations. Several sensitivity analyses will be performed to examine the impact of assumptions on study conclusions.

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)

Drug registry

Other

Data sources (types), other

Exposure 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