# Psoriasis Study of Health Outcomes – an International Observational Study of 3 Year Health Outcomes in the Biologic Treatment of Moderate to Severe Plaque Psoriasis (PSoHO)

**First published:** 30/05/2018
**Last updated:** 02/04/2024

Study | Ongoing

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/46014

**EU PAS number**
EUPAS24207

**Study ID**
46014

**DARWIN EU® study**
No

**Study countries**
Argentina
Australia
Austria
Brazil
Canada
Colombia
France
Germany
Hungary
Israel

Italy
Korea, Republic of
Mexico
Netherlands
Poland
Portugal
Romania
Saudi Arabia
Spain
Switzerland
Taiwan
United Arab Emirates
United Kingdom

**Study description**
In order to evaluate the additional benefit of improved skin clearance for patients with psoriasis and the associated long term outcomes including patient reported HRQoL and health care resource consumption, the currently proposed study will explore the clinical effectiveness of anti IL 17A treatments (specifically ixekizumab and secukinumab) in patients with moderate to severe psoriasis compared to other biologic treatments within routine care.

**Study status**
Ongoing

# Research institution and networks

## Institutions

### United BioSource Corporation (UBC)
Switzerland
**First published:** 25/04/2013
Last updated
06/03/2024
Institution
Non-Pharmaceutical company
ENCePP partner

## Contact details

**Study institution contact**
Catherine Reed

Study contact

reed_catherine@lilly.com
**Primary lead investigator**
Catherine Reed
Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Actual:
02/03/2018

**Study start date**
Planned:
29/06/2018
Actual:
16/07/2018

**Date of final study report**
Planned:
20/11/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## Regulatory

**Was the study required by a regulatory body?**
No

**Is the study required by a Risk Management Plan (RMP)?**
Not applicable

# Methodological aspects

## Study type

### Study type list

**Study type:**
Non-interventional study

**Scope of the study:**
Effectiveness study (incl. comparative)

**Main study objective:**
To compare the proportion of patients with moderate to severe plaque psoriasis treated in clinical practice with ixekizumab or secukinumab (the anti IL 17A cohort) relative to other biologic treatments who achieve clear or almost clear skin (equivalent to PASI 90 or higher and/or sPGA 0/1) at 12±4 weeks following initiation of or switching to a new biologic

# Study Design

**Non-interventional study design**
Cohort

# Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**
IXEKIZUMAB
SECUKINUMAB
BRODALUMAB
USTEKINUMAB
ADALIMUMAB
ETANERCEPT
INFLIXIMAB
GUSELKUMAB
TILDRAKIZUMAB

**Medical condition to be studied**
Psoriasis

# Population studied

**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**
2000

## Study design details

**Outcomes**
PASI, sPGA, BSA, DLQI

**Data analysis plan**
Logistic regression will be used to analyze the proportions of the primary endpoint for assigned anti IL 17A and other biologic treatments. In addition to the treatment groups, the propensity scores derived during baseline interim analyses will be included as covariates into the model.

# Data management

## Data sources

**Data sources (types)**
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