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

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 institutions 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

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Study contact

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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

2.000

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