Psoriatic Arthritis Observational Study of Persistence of Treatment (PRO-SPIRIT Study)

First published: 29/08/2019

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS31174

Study ID

31175

DARWIN EU® study

No

Study countries

Canada

France

Germany

Italy

Spain

United Kingdom

Study description

The present observational study is to describe the 24-month persistence alongside effectiveness and healthcare resource use associated with bDMARD and tsDMARD treatments for PsA.

Study status

Planned

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Tamas Treuer treuert@lilly.com

Study contact

treuert@lilly.com

Primary lead investigator

Tamas Treuer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2019

Study start date
Planned: 31/10/2019

Date of final study report
Planned: 31/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & 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:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To describe persistence at 24 months among patients with PsA who initiate a new bDMARD or tsDMARD treatment including any tumor necrosis factor inhibitor (TNFi), ustekinumab, apremilast, ixekizumab, secukinumab, and tofacitinib, regardless of the line of therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IXEKIZUMAB

SECUKINUMAB

TOFACITINIB

USTEKINUMAB

APREMILAST

Anatomical Therapeutic Chemical (ATC) code

(L04AB) Tumor necrosis factor alpha (TNF-alpha) inhibitors

Tumor necrosis factor alpha (TNF-alpha) inhibitors

Medical condition to be studied

Psoriatic arthropathy

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

1620

Study design details

Outcomes

Persistence, PGA, HAQDI, PSAD

Data analysis plan

Persistence at Month 24 will be evaluated by Kaplan-Meier analysis of the time spent usingthe same bDMARD or tsDMARD initiated at baseline.

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)

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