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

PURI

https://redirect.ema.europa.eu/resource/31175

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

Study contact

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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

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