Persistence and adherence to novel systemic pharmacological treatment of moderate to severe psoriasis vulgaris and psoriatic arthritis – A register-based cohort study in Finland and Sweden

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Study Ongoing

Administrative details

EU PAS number

EUPAS28564

Study ID

50021

DARWIN EU® study

No

Study countries

- ☐ Finland
- ☐ Sweden

Study description

Psoriasis is a noncommunicable complex and multifactorial immune-mediated inflammatory disease, occurring in the skin and often involves joints. The most common form of psoriasis (90% of cases) is psoriasis vulgaris (PsV, also known as plaque psoriasis), resulting in inflamed itchy skin, mostly manifesting on the scalp, elbows, and knees. Approximately 30% of PsV patients develop psoriatic arthritis (PsA), chronic inflammatory arthritis, where in addition to the skin manifestation, joints are also affected with pain, swelling and stiffness. In about 80% of PsA patients, arthritis manifestation follows to the PsV development. These diseases are incurable, and the aim of the treatment is symptom remission. Novel systemic drugs, including biologic drugs targeting immunomodulating cytokines and the phosphodiesterase 4 inhibitor apremilast, can be used for the treatment of moderate to severe symptoms of these diseases. Since PsV and PsA are considered as chronic diseases, long-term treatment is necessary to maintain efficacy. The real-world evidence on the treatment patterns of biologics and apremilast in the Nordic countries is limited. The main aim of this retrospective, population- and register-based cohort study is to investigate the persistence and adherence of drugs dispensed from community pharmacies for patients with moderate to severe psoriasis vulgaris. The study will include persons who initiate treatment with adalimumab, brodalumab, etanercept, ustekinumab, secukinumab, ixekizumab, guselkumab, certolizumab pegol, tildrakizumab, or apremilast in Finland and Sweden during the study period of 2008-2020. The treatment patterns of interest include treatment gaps and restarts as well as switches during a follow-up period of up to 13 years. The study will be based on nationwide registers.

Study status

Ongoing

Research institutions and networks

Institutions

IQVIA

United Kingdom

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Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Laura Saarelainen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/09/2018

Study start date

Planned: 01/07/2019

Actual: 14/05/2019

Data analysis start date

Planned: 30/08/2019

Actual: 01/11/2019

Date of interim report, if expected

Planned: 31/12/2019

Actual: 31/12/2020

Date of final study report

Planned: 31/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen Pharmaceutica NV

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:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main aim of this study is to investigate the persistence and adherence of drugs dispensed from community pharmacies for patients with moderate to severe psoriasis vulgaris.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA32) apremilast

apremilast

(L04AB01) etanercept

etanercept

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AC05) ustekinumab

ustekinumab

(L04AC10) secukinumab

secukinumab

(L04AC12) brodalumab

brodalumab

(L04AC13) ixekizumab

ixekizumab

(L04AC16) guselkumab

guselkumab

(L04AC17) tildrakizumab

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

17000

Study design details

Outcomes

The primary outcomes of this study are persistence, proportion of persistent patients, time to non-persistence, hazard ratios associated with non-persistence, adherence, proportion of adherent patients, non-adherence, and odds ratios associated with non-adherence. The secondary outcomes of this study are patient characteristics (e.g. sociodemographic data, comorbidities, resource utilization, and prior use of conventional systemic treatment for psoriasis vulgaris) for persons initiating treatment with each study drug, and treatment patterns, including treatment gaps, switching, and restart, during the study period.

Data analysis plan

All dispensations of the study drugs during the study period will be included in the analyses. Drug supply will be defined for each dispensation on the basis of number and contents of dispensed package(s) and the dosage instructions according to the summary of product characteristics for the particular drug. MPR, based on the drug supplies, will be used to measure drug adherence. Continuous exposure periods will be defined on the basis of drug supplies and by applying more detailed rules for times when drug exposure periods end. The continuous exposure periods will be used to define PDC by each drug, and to determine treatment persistence. The characteristics of patients initiating treatment with study drugs will be described. Adherence and persistence will be described and compared across study drugs using regression models. Rates of drug switches, restarts, treatment gaps and number and duration of treatment lines will be investigated. Various sensitivity analyses will be performed.

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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish prescribed drug register, NorPD

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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