Managing PSOriasis in the REAL world: One-year prospective, observational study of the journey of patients with plaque psoriasis prescribed calcipotriol/betamethasone aerosol foam or other topical therapy (PSOREAL)

First published: 27/01/2022

Last updated: 10/02/2022

Study | Finalised

Administrative details

EU PAS number

EUPAS45322

Study ID

45655

DARWIN EU® study

No

Study countries

Canada

Sweden

United Kingdom

Study description

12-months non-interventional, multinational, multi-site study in a prospective cohort study of adult patients suffering from psoriasis vulgaris and treated with topical therapy.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 101 centres are involved in the study

Contact details

Study institution contact

Pharmacoepidemiology LEO Pharma ogvdk@leo-pharma.com

Study contact

ogvdk@leo-pharma.com

Primary lead investigator

Pharmacoepidemiology LEO Pharma

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 21/03/2016

Study start date

Actual: 12/01/2017

Date of final study report

Actual: 10/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LEO Pharma

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To describe and compare real-world short-term treatment success with calcipotriol/betamethasone foam and other topical psoriasis treatments. To describe and compare calcipotriol/betamethasone foam and other topical psoriasis treatments regard-ing the long-term real-world success of the initial treatment strategy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Enstilar

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Adult patients suffering from psoriasis vulgaris and treated with topical therapy.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

1214

Study design details

Outcomes

Proportion of patients reporting Patient reported Psoriasis Global Assessment (PaGA) success (defined as clear or almost clear skin at the end of the initial treatment period). EuroQol 5 dimensions/five levels questionnaire EQ-5D-5L Dermatology Life Quality Index DLQI Psoriasis Symptom Inventory PSI Treatment satisfaction

---

Data analysis plan

Descriptive statistics. Effectiveness endpoints are analysed using crude and adjusted regression models.

Documents

Study results

PSOREAL NIS report summary Final.pdf (171.58 KB)

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