Prospective, observational, non-interventional, multicenter study to investigate treatment outcomes and patient satisfaction of Enstilum® foam (calcipotriol/betamethasone aerosol foam) as topical treatment of adult patients with psoriasis under the routine practice in Korea

First published: 07/01/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS38883

Study ID

45566

DARWIN EU® study

No

Study countries

Korea, Republic of

Study status

Ongoing

Research institutions and networks

Institutions

Seoul National University Bundang Hospital

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Institution

Contact details

Study institution contact

Choi Sun snckr@leo-pharma.com

Study contact

snckr@leo-pharma.com

Primary lead investigator

Yoon Sang Woong

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 12/05/2020

Actual: 12/05/2020

Study start date
Planned: 28/05/2020

Actual: 28/05/2020

Date of final study report
Planned: 10/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LEO Pharma Korea

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:

This study aims to investigate treatment outcomes and patient satisfaction of Enstilum® foam under routine practice conditions. Korean patient profile for selected day-to-day therapies including Enstilum® foam and the therapy(ies) used prior to Enstilum® foam will be investigated through this study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Enstilum

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

218

Study design details

Outcomes

the proportion and 95% confidence interval of "treatment success" subjects in IGA at week 4, Change of severity of psoriasis, PASI50, PASI75, Change of PASI, Change of symptoms, clinically significant itch relief, satisfaction with Enstilum® foam, Change of DLQI, subjects achieving a DLQI ≤ 5 points, correlation between baseline severity and drug consumption, exploratory endpoints in subgroup analysis by initial plaque size, drug consumption, frequency of treatment

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Data analysis plan

Data processing and statistical analysis will be carried out with SAS software version 9.4 or a more recent version. The following populations are evaluated: • The safety analysis will be performed for a subset of the all patients who have submitted a written consent to use their data in this study and who have reported using Enstilum® foam at least once. • The exploratory analysis will be performed for subgroup of the safety evaluation and includes all patients for which additionally primary endpoint variable has been documented at least once. In accordance with the non-interventional nature of NIS, the statistical

analysis is descriptive and exploratory. All collected variables are listed and described by graphical representations or frequency or characteristic tables. As far as statistical tests are calculated, they have exploratory character and did not serve the confirmatory test before the examination of formulated hypotheses. An α-adjustment is not made.

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, medical chart, worksheet

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