Non-interventional Study report synopsis

PSOREAL: 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.

Design of study:

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.

Sponsor:	LEO Pharma A/S
Study identifier:	NIS-Enstilar-1285
ClinicalTrials.gov number:	NCT2935582
Date of study initiation:	12-Jan-2017
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Synopsis version:	1.0

Research question and objectives

The study aimed to describe the current topical treatment patterns for psoriasis and the outcomes of these treatments, including the calcipotriol/betamethasone dipropionate foam fixed combination product (Cal/BD foam) when used in the diversity of the real-life setting with local differences in access to drugs and current treatment practices, and regional cultural differences, and adult patients of all backgrounds, sex, socio-economic standing, health background, comorbidity and co-medication.

- *Primary objectives*
  - To describe and compare real-world short-term treatment success with Cal/BD foam and other topical psoriasis treatments.
  - To describe and compare Cal/BD foam and other topical psoriasis treatments regarding the long-term real-world success of the initial treatment strategy.

Study design

This was a 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.

The study aimed to enrol patients in a fixed sequence where 1 patient planned for treatment with Cal/BD foam should be followed by 2 patients planned to receive another topical treatment for psoriasis. The initial topical treatments were categorized as follows:

1. Cal/BD foam
2. Other calcipotriol/betamethasone dipropionate combination products, ointment (Cal B/D ointment)
3. Other calcipotriol/betamethasone dipropionate combination products, gel (Cal B/D gel)
4. Monosteroid products and monosteroid products in combination with Vitamin D analogues
5. Any other topical treatment (including vitamin D analogues, keratolytics, and emolients)

If patients were prescribed more than one topical treatment, the treatment highest on the above list determined the category.

Investigators were expected to enter data at baseline and at any patient contact throughout the duration of the study, with a medical chart review of data completeness and CRF sign-off after 1 year. After the baseline visit patients got access to the online platform where they were expected to enter data on their electronic device before and after the initial treatment period. The length of the initial treatment period could vary by treatment, but patients were prompted by e-mail reminders to provide data 4 weeks after the start of the initial treatment.

Short-term effectiveness objectives were addressed using the patient-reported data focusing on the initial treatment period (~4 weeks). Long-term effectiveness objectives were addressed using data from the entire 12 months period and were based on the physician-reported data from contacts as well as the event-driven data collection from patients.

Endpoints

For analysis of real-world short-term effectiveness of topical psoriasis treatments, the following endpoints were used:

- Proportion of patients reporting Patient reported Psoriasis Global Assessment (PaGA) success (defined as clear or almost clear at the end of the initial treatment period).
- Itch score change 1 week after treatment initiation, based on the Psoriasis Symptom Inventory (PSI) questionnaire, 7-day version (defined as 'success' when reported as ≤1).
- Itch score success at the end of initial treatment, based on the Psoriasis Symptom Inventory (PSI) questionnaire, 7-day version (defined as 'success' when reported as ≤1).

The long-term real-world success of the initial treatment strategy was evaluated by:

- Time to first switch of treatment strategy.
- Time to first flare-up after initial treatment completion.
- Treatment satisfaction at the end of initial treatment.

Setting

The study was conducted in 101 sites in 3 countries in Europe and North America (United Kingdom, Sweden, and Canada).

Results

A total of 1214 patients were enrolled. Of these patients, the majority were from the United Kingdom (N=761), and fewer were from Canada (N=349) or Sweden (N=104). The overall enrolled study population included a smaller fraction of patients who were using systemic treatment at enrolment (N=208). No statistical analyses were prepared for this population due to the low number of patients when divided in the 5 treatment groups ('Cal/BD foam', 'Cal/BD ointment', 'Cal/BD gel', 'Monosteroids' or 'Other topical').

In the study population not using systemics (N=1006). Slightly more than one-third (N = 394/1006) were treated with Cal/BD foam as the initial treatment. The mean (SD) age was ~50 years, BMI of 29.7 (17.8) kg/m2, BSA of 9.7% (12.9), and the majority of patients had a PGA score of mild or moderate at baseline. Approximately half of the population were males.

At the end of the initial treatment period 41.3% contributed data to evaluate the primary endpoint 'PaGA treatment success'. In these patients, the proportion who reported clear/almost clear skin at the end of initial treatment (PaGA treatment success) ranged from 32.1% in the 'Cal/BD foam' group to 11.5% in the 'other topicals' groups. In multivariate analysis, a statistically significant difference was seen between Cal/BD foam and the 'other topical' group while no statistically significant difference was seen between 'Cal/BD foam' and any of the other treatment groups.

Itch score success 1 week after treatment initiation was not statistically significantly different (unadjusted or adjusted model) between Cal/BD foam and any of the other treatment groups. However, itch score success at the end of the initial treatment was significantly higher with Cal/BD foam vs the 'other topical' group.

Very few data were available to evaluate the long-term treatment success and treatment satisfaction. For 228 patients at least one switch was reported. At least one flare-up was reported by 123 patients. The total number of switches and flare-ups reported was unrealistically low and therefore most likely considerably underreported. Although there was tendency in favour of Cal/BD foam for these endpoints, no statistically significant differences were seen.

Discussion

A major limitation in the PSOREAL study is the large amount of missing data affecting both the short- and long-term endpoints. The primary short-term effectiveness endpoints were based on patient-reported data from less than half of the patients.

For the long-term data the degree of incompleteness is difficult to determine. Although few patients actively discontinued their study participation, the number of visits, treatment switches and flare-ups were considerably lower than what would be expected in this population and therefore these results should be interpreted very cautiously.

To the best of our knowledge, this is the first study to report the current treatment patterns and the treatment outcomes of the Cal/BD foam fixed combination product for topical treatment of psoriasis and other topical psoriasis treatments, in a real-life setting over a period of 1 year. Despite the limitations, the results indicate that users of Cal/BD foam experience clinical and quality of life improvements during the initial treatment. Furthermore, the study indicated that Cal/BD foam is well tolerated among users in real world setting.