Safety and Effect of LEO 90100 aerosol foam on the HPA Axis and Calcium Metabolism in Adolescent Subjects (Aged 12 to < 17 Years) with Plaque Psoriasis
A phase 2 trial evaluating the safety and efficacy of once daily topical treatment with LEO 90100 aerosol foam in adolescent subjects with plaque psoriasis

Published: 17-11-2015
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The objective of the present phase 2 trial is to evaluate the safety, pharmacodynamics (effect on HPA axis and calcium metabolism) and pharmacokinetics of LEO 90100 in adolescent subjects with plaque psoriasis. Subjects will be treated once daily…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON42757

Source
ToetsingOnline

Brief title
A 4-week trial in adolescent subjects with plaque psoriasis.

Condition

- Epidermal and dermal conditions

Synonym
Plaque Psoriasis, Psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: Leo Pharma
Source(s) of monetary or material Support: LeoPharma

Intervention

Keyword: Plaque Psoriasis, Psoriasis

Outcome measures

Primary outcome

* Adverse events (AEs)

* Subjects with serum cortisol concentration of <=18 mcg/dl at 30 minutes after ACTHchallenge at Week 4

* Change in albumin-corrected serum calcium from baseline (SV2) to Week 4

* Change in calcium excretion from baseline (SV2) to Week 4 in 24-hour urine

* Change in calcium:creatinine ratio from baseline (SV2) to Week 4 in 24-hour urine

Secondary outcome

* Subjects with serum cortisol concentration of <=18 mcg/dl at both 30 and 60 minutes after ACTH-challenge at Week 4

* Change in calcium:creatinine ratio from baseline (SV2) to Week 4 in spot urine

* Subjects with *treatment success* (i.e., *clear* or *almost clear* for subjects with at least *moderate* disease at baseline, *clear* for subjects with *mild* disease at baseline) according to the physician*s global assessment

of disease severity on the body at Week 4

* Subjects with *treatment success* (i.e., *clear* or *almost clear* for subjects with at least *moderate* disease at baseline, *clear* for subjects with *mild* disease at baseline) according to the physician*s global assessment of disease severity on the scalp at Week 4

* Percentage change in psoriasis area and severity index (PASI) from baseline (V1) to Week 4

* Subjects with *treatment success* (i.e., *clear* or *very mild) according to the subject*s global assessment of disease severity on the body at Week 4

* Subjects with *treatment success* (i.e., *clear* or *very mild) according to the subject*s global assessment of disease severity on the scalp at Week 4

* Change in itch as assessed by the Visual Analogue Scale (VAS) from baseline (V1) to Week 4

Study description

Background summary

The majority of affected subjects has mild to moderate disease and can be treated with topical therapies. In the group of subjects with moderate to severe psoriasis topical therapies are also appropriate either as adjunct to phototherapy, systemic or biologic agents. One of the advantages of topical therapies is a reduced risk of systemic toxicity compared to other treatment modalities. The most commonly used topical therapies in adults are corticosteroids and vitamin D analogues used either alone or in combination.

The fixed combination of calcipotriol 50 mcg/g (as monohydrate) and betamethasone 0.5 mg/g (as dipropionate) in an ointment and gel/topical suspension formulation for body and scalp have already been marketed for several years in adults. These products are marketed in the US under the trade name Taclonex® and in Europe under trade names such as Daivobet®, Dovobet® and Xamiol®. FDA has recently granted approvals for the treatment of scalp

psoriasis with Taclonex® Topical suspension in adolescent patients aged 12-17 years and treatment of psoriasis vulgaris with Taclonex® Ointment in adolescent patients aged 12-17 years.

Psoriasis is a chronic, recurrent disease, and no cure exists. Despite availability of current treatment options, many subjects are not achieving optimal control of their psoriasis. Patient adherence may be the largest barrier to treatment success with topical therapies. The factors that hinder patient adherence include frustration with medication efficacy, messiness and time-consuming and inconvenient application, among others.

To address this need, LEO has developed a new formulation of calcipotriol/betamethasone dipropionate (BDP) which was demonstrated to be more effective than Daivobet ® ointment with a similar safety profile in adults, including systemic safety. The foam formulation may be cosmetically more acceptable and user friendly than ointment and therefore potentially lead to better adherence.

Study objective

The objective of the present phase 2 trial is to evaluate the safety, pharmacodynamics (effect on HPA axis and calcium metabolism) and pharmacokinetics of LEO 90100 in adolescent subjects with plaque psoriasis. Subjects will be treated once daily over a period of 4 weeks.

Study design

This will be an international, multi-centre, prospective, open-label , non-controlled, singlegroup, 4-week trial in adolescent subjects (aged 12 to < 17 years) with plaque psoriasis on the body and scalp.

De patiënten zullen plaatselijke behandeling ontvangen met LEO 90100 een maal per dag voor maximaal 4 weken. De onderzoeksduur van elke patiënt (inclusief een 4-weekse uitwasperiode) is 8 weken en omvat 5 bezoeken aan de kliniek (tot 7 keer als er een follow-up bezoek is vereist).

Intervention

See Study population (in English)

Study burden and risks

If your child participates in this study, he or she will receive a new drug. Little is known about the effects and side effects of this medicine in children. This is a disadvantage. If the treatment improves the disorder, this will be an advantage.

Research on blood samples of your child's supplies may not directly benefit your child. However, the information may be useful in order to develop new treatments for psoriasis and identify patients who can benefit from treatment in the future.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Main criteria for inclusion (all subjects)
- Adolescent subjects (age 12 to 16 years, 11 months).
- Plaque psoriasis on trunk and/or limbs affecting at least 2% BSA.
- Plaque psoriasis on the scalp affecting at least 10% of total scalp area.
- A total psoriatic involvement on trunk, limbs and scalp not exceeding 30% BSA.
- PGA score of at least mild on trunk and/or limbs at SV1, SV2 and V1.

- PGA score of at least mild on scalp at SV1, SV2 and V1.
- A serum albumin-corrected calcium below the upper reference limit at SV2.
- Female subjects must be of either
* non-childbearing potential, i.e. premenarchal or have a confirmed clinical history of sterility (e.g. the subject is without a uterus or has tubal litigation) or,
* child-bearing potential provided there is a confirmed negative pregnancy test prior to trial treatment to rule out pregnancy.
- Female subjects of child-bearing potential must be willing to use highly effective contraception at trial entry and until completion.;Main criteria for inclusion (for subjects undergoing HPA axis testing:)
- Plaque psoriasis on trunk and/or limbs affecting at least 10% BSA.
- Plaque psoriasis on the scalp affecting at least 20% of total scalp area.
- PGA score of at least moderate on trunk and limbs at SV1, SV2 and V1.
- PGA score of at least moderate on scalp at SV1, SV2 and V1.
- Normal HPA axis function at SV2 (serum cortisol concentration above 5 mcg/dl before ACTH challenge and serum cortisol concentration above 18 mcg/dl 30 minutes after ACTH challenge).

Exclusion criteria

Main criteria for exclusion (for all subjects):
- A history of hypersensitivity to any component of LEO 90100.
- Systemic treatment with biological therapies (marketed or not marketed), with a possible effect on scalp and/or body psoriasis within the following time period prior to V1 and during the trial:
a. etanercept - within 4 weeks prior to V1
b. adalimumab, infliximab - within 2 months prior to V1
c. ustekinumab - within 4 months prior to V1
d. experimental products - within 4 weeks/5 half-lives (whichever is longer) prior to V1
- Systemic treatment with therapies other than biologicals, with a possible effect on scalp and/or body psoriasis (e.g. methotrexate, retinoids, immunosuppressants) within 4 weeks prior to V1 or during the trial.
- PUVA therapy within 4 weeks prior to V1.
- UVB therapy within 2 weeks prior to V1 or during the trial.
- Any topical treatment on the scalp and body including corticosteroids and vitamin D (except for emollients and non-steroid medicated shampoos) within 2 weeks prior to V1 or during the trial.
- Systemic calcium, vitamin D supplementation > 400 IU/day, antacids, diuretics, antiepileptics, diphosphonates or calcitonin within 4 weeks prior to SV2 or during the trial. (note: stable dose of vitamin D supplementation <= 400 IU/day is permitted provided there are no dose adjustments during the study period).;Main criteria for exclusion (for subjects undergoing HPA axis testing:)
- A history of serious allergy, allergic asthma or serious allergic skin rash.
- Known or suspected hypersensitivity to any component of CORTROSYN®/Synacthen®(including ACTH/cosyntropin/tetracosactide)

- Systemic treatment with corticosteroids (including inhaled and nasal steroids) within 12 weeks prior to SV2 or during the trial.
- Oestrogen therapy (including contraceptives) or any other medication known to affect cortisol levels or HPA axis integrity within 4 weeks prior to SV2 or during the trial.
- Enzymatic inductors (e.g., barbiturates, phenytoin, rifampicin) within 4 weeks prior to SV2 or during the trial.
- Systemic or topical cytochrome P450 inhibitors (e.g., ketoconazole, itraconazole,metronidazole) within 4 weeks prior to SV2 or during the trial. Topical ketoconazole within 2 weeks prior to SV2.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	LEO90100
Generic name:	NA

Ethics review

Approved WMO

Date:	17-11-2015

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-000839-33-NL
ClinicalTrials.gov	NCT02387853
CCMO	NL54553.091.15