Optimising outpatient care in mild to moderate psoriasis by a newly developed *Topical Treatment Optimising Programme* - an international study using Daivobet®/Dovobet® Gel (*PSO-TOP*)

Published: 13-12-2011
Last updated: 30-04-2024

The objective of the study is to assess the value of the *Topical Treatment Optimising Programme* in the topical treatment, which will be use together with the standard treatment, of insufficiently treated mild to moderate psoriasis after 8 weeks of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON37524

Source
ToetsingOnline

Brief title
PSO-TOP

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
plaque psoriasis, psoriasis

Research involving
Human

Sponsors and support

Primary sponsor: SCIderm GmbH
Source(s) of monetary or material Support: SCIderm GmbH;Hamburg;Germany;Prof. Dr. Kristian Reich (non-profit)

Intervention

Keyword: Daivobet/Dovobet, Phase IV, Psoriasis, TTOP

Outcome measures

Primary outcome

Rate of patients with a PGA (as defined by Langley and Ellis 2004) of 0 or 1 at

week 8.

Secondary outcome

1) Rate of patients with a PGA (as defined by Langley and Ellis 2004) of 0 or 1

at weeks 16 to 64 (documented at intervals of 8 weeks)

2) Mean PGA and BSA at weeks 8 to 64 (documented at intervals of 8 weeks)

3) EQ-5D, EQ-VAS and DLQI at weeks 0, 8, 32 and 64

4) Rate of patients achieving DLQI * 5 at weeks 0, 8, 32 and 64

5) Exploratory Patient Reported Outcomes: TTQ, PPQ and PsGA at weeks 0, 8, 32

and 64

6) Results of TTOP element ranking by the patient (only TTOP intervention arm)

at weeks 8 and 64

7) Rate of patients reaching a PsGA score of 0 or 1 at weeks 8 to 64 in the

single countries (documented at intervals of 8 weeks)

8) Days away from work/studies due to psoriasis

9) Mean weight of returned study medication at weeks 4 to 64 (documented at

intervals of 4 to 8 weeks)

10) Drop-out rate per study arm at week 64

11) Rates of AEs and SAEs

Study description

Background summary

For patients how are diagnosed with chronic psoriasis are adherence to long treatment period essential to achieve optimal results. A third part of the patients who received a prescription did not redeem it in the pharmacy. The correct number of medication applications per day declined over time (only 77% after 2 weeks and only 50% after 8 weeks) and the deficient adherence (not using the medication at all or using too little of the medication) also leads to an inefficient use of health care resources and creates a considerable loss to society. Poor adherence in psoriasis also increases risks for the development of concomitant diseases, such as depression, inflammation-related CHD/stroke, diabetes and cancer.

It has been shown that if the physician is perceived as friendly and as a person who understands the burden of SCIderm GmbH Confidentialdisease for the patient, that this will lead to improved treatment outcomes. It has also been shown that the patient*s education and awareness of his disease will increase therapy adherance.

The purpose of this clinical study is to evaluate whether a specifically developed Topical Treatment Optimising Programme (TTOP), which will be offered to one half of the patients in this study, is able to further increase the therapeutic success of the topical treatment of plaque psoriasis.

TTOP is a standardised programme, in which the patient is taken care of in an intensified, optimised manner. On top of pharmaceutical care (study medication), TTOP offers a per-sonalised general health care programme that includes one-to-one visits with the investiga-tor and the study nurse as well as the opportunity to contact the study nurse in between the visits.

Study objective

The objective of the study is to assess the value of the *Topical Treatment Optimising Programme* in the topical treatment, which will be use together with

the standard treatment, of insufficiently treated mild to moderate psoriasis after 8 weeks of once daily treatment with Daivobet®/Dovobet® Gel.

Study design

This is a phase IV, multicentre, randomised, controlled, inter-individual parallel group study to evaluate the efficacy of the TTOP in patients with mild to moderate psoriasis. The study will last 64 weeks (about 15 months) and contains 10 visits (week 0, 4, 8,16, 24, 32, 40,48, 56 and 64). Additional visits might become necessary due to safety reasons.
The study medication Daivobet®/Dovobet® Gel should be applied once daily to affected areas within the first eight weeks of treatment (i.e. up to Visit 3). After Visit 3, Daivobet®/Dovobet® Gel should be used as needed, but not more often than once daily.

The Subjects will be allocated in a 1:1 ratio to one of the study arms at Visit 1 (week 0):
- TTOP * arm (intervention-arm) Standard treatment of mild to moderate psoriasis with Daivobet®/Dovobet® Gel plus
participation in the Topical Treatment Optimising Programme
- non-TTOP * arm (comparator-arm) Standard treatment of mild to moderate psoriasis with Daivobet®/Dovobet® Gel without participation in the Topical Treatment Optimising Programme

During the visits the subject needs to complete the following questionriares: Psoriasis Area and Severity Index (PASI), percentage of the Body Surface Area (BSA) affected by psoriasis, the Physician*s Global Assessment score (PGA), subjects disease status (PsGA), Topical Therapy Questionnaire (TTQ), Patient Preference Questionnaire (PPQ), quality of life status (DLQI and EQ-5D questionnaires).

Intervention

Following confirmation of eligibility, subjects will be randomized in a 1:1 ratio to one of the study arms at Visit 1 (week 0):
- TTOP * arm (intervention-arm) Daivobet®/Dovobet® Gel with TTOP or;
- non-TTOP * arm (comparator-arm) Daivobet®/Dovobet® Gel without TTOP.

The standard investigational drug for all patients will be Daivobet®/Dovobet® Gel (50 micrograms calcipotriol/0.5 mg betamethasone/g). Daivobet®/Dovobet® Gel contains two active substances: calcipotriol and betamethasone. The study medication Daivobet®/Dovobet® Gel should be applied once daily to affected areas within the first eight weeks of treatment (i.e. up to Visit 3). After Visit 3, Daivobet®/Dovobet® Gel should be used as needed, but not more often than once daily.

Study burden and risks

Like every medicine, Daivobet®/Dovobet® Gel can cause side effects, although not every-body gets them. According to the Package Leaflet for Daivobet®/ Dovobet® Gel approximately 1 in 12 people may experience side effects; but most of these are reactions at the site where the gel has been applied.

Serious side effects Daivobet®/Dovobet® Gel.
Uncommon (affect less than 1 in 100 people):
* Worsening of the psoriasis;

Additional serious side effects are known to be caused by betamethasone:
* Adrenal glands may stop working properly: Signs are tiredness, depression and anxiety;
* Cataracts (signs are cloudy and foggy vision, difficulty of seeing at night and hyper-sensitivity to light) or an increase in pressure inside your eye (signs are eye pain, red eye, decreased or cloudy vision),
* Infections
* Pustular psoriasis
* Impact on the metabolic control of diabetes mellitus

Additional serious side effects known to be caused by calcipotriol:
* Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and trouble breathing may occur.
* Treatment with this gel may cause the level of calcium in blood or urine to in-crease

Less serious side effects Daivobet®/Dovobet® Gel:
* Common (affect less than 1 in 10 people)
* Itching
* Uncommon (affect less than 1 in 100 people)
* Eye irritation
* Burning sensation of the skin
* Skin pain or irritation
* Inflammation or swelling of the hair root (folliculitis)
* Rash with inflammation of the skin (dermatitis)
* Redness of the skin due to widening of the small blood vessels (erythema)
* Acne (pimples)
* Dry skin
* Rash
* Pustular rash

Additional less serious side effects caused by application of betamethasone * especially after long-term-usage - include the following:
* Atrophy (thinning and fragility) of the skin

* Appearance of surface veins or stretch marks
* Hypertrichose (increased hair growth)
* Red rash around the mouth (perioral dermatitis)
* Skin rash with inflammation or swelling (allergic contact dermatitis)
* Appearance of small white papules in the skin (colloid milia)
* Depigmentation (lightening of skin colour).
* Additional less serious side effects known to be caused by calcipotriol include the following

Additional less serious side effects known to be caused by calcipotriol:
* Photosensitivity
* Eczema.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male and female patients aged at least 18 years
- Mild to moderate active plaque psoriasis with a PGA * 2 on the 7 point scale by Langley and Ellis and a Body Surface Area (BSA) of * 10%
- Topical psoriasis treatment with coal or tar preparations, tazarotene, steroids, or vitamin D analogues, or combinations of steroids and vitamin D analogues (except gel combination products containing 50 micrograms calcipotriol / 0.5 mg betamethasone/g) or dithranol and its combination preparations over the last 8 weeks prior to Visit 1 (week 0)
- Written informed consent to participate in the study has been given prior to any study related procedures

Exclusion criteria

- Severe renal insufficiency
- Severe hepatic disorders
- Known hyper calcaemia
- Erythrodermic, exfoliative, pustular or guttate psoriasis
- Facial or genital psoriasis
- Fulfilment of at least one contraindication according to the Summary of Product Characteristics of Daivobet®/Dovobet®
- Pregnant and/or breast-feeding women
- Hypersensitivity to the active substances or to any of the excipients
- Suspected non-compliance with the clinical study procedures
- Current participation in another clinical study
- Systemic treatment with biological therapies, whether marketed or not, with a possible effect on psoriasis vulgaris within the following time periods prior to Visit 1 (week 0):
* etanercept * within 4 weeks prior to Visit 1 (week 0)
* adalimumab, alefacept, infliximab * within 2 months prior to Visit 1 (week 0)
* ustekinumab * within 4 months prior to Visit 1 (week 0)
* experimental products * within 4 weeks/5 half-lives (whichever is longer) prior to Visit 1 (week 0)
- Phototherapy within the following time periods prior to Visit 1 (week 0):
* PUVA * within 4 weeks prior to Visit 1 (week 0)
* UV-B * within 2 weeks prior to Visit 1 (week 0)

Study design

Design

Study phase: 4

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2012
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Daivobet/Dovobet Gel
Generic name:	calcipotriol / betamethasone
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	21-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	06-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	13-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2011-001697-26-NL
CCMO	NL38121.018.11

Study results

Date completed:	08-09-2014

Actual enrolment: 70

Summary results
Trial is onging in other countries