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Pharmacokinetics of calcipotriol after Daivonex® cream application

Submission date	Recruitment status	[X] Prospectively registered
04/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/12/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2017	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Psoriasis is a chronic (long lasting) skin condition that causes red, flaky and crusty patches (or plaques) of skin, usually on the elbows, knees, scalp and lower back, that are covered with silvery scales. The severity of the condition varies a lot, but most sufferers only have small patches of skin that are affected. They can, however, be itchy or sore and, for some people, the condition has a major impact on their quality of life. Topical vitamin D analogues (creams that have the therapeutic properties of vitamin D but without any harmful side effects) are used as both a primary (first choice) and adjunctive therapy (used in combination with another treatment) for mild to moderate plaque psoriasis and have been used successfully and safely for over a decade. Calcipotriol is the most important topical synthetic (man-made) vitamin D analogue used in the treatment of psoriasis. Calcipotriol cream (Daivonex®, LEO Pharma S.p.A., Italy) is used for psoriasis as monotherapy maintenance treatment (that is, as a treatment on its own to help keep prevent symptoms) and in combination with topical corticosteroids (steroid creams). The aim of this study is to investigate the pharmacokinetic profile of calcipotriol in plasma (that is, how the drug is absorbed, carried around the body, used by the body and then removed) in healthy men after a single and also multiple doses of Daivonex® 0.005% cream over a period of 1 week, twice a day.

Who can participate?
Healthy men aged between 18 and 55

What does the study involve?
Each participant is given 7g of Daivonex® 0.005% cream, applied by the Investigator on their back, twice a day for 7 consecutive days. The cream is applied to a 35x35cm area, with the application taking a maximum of 3 minutes, ensuring the cream is applied evenly over the selected area.

What are the possible benefits and risks of participating?
No real potential benefits are foreseen to the volunteers participating in this study. No particular risks are expected for the study subjects at the dose regimen of the present study. After application of Daivonex® cream, local, temporary, irritation may occur. Hypersensitivity reactions have been reported, including rare cases of angioedema (skin swelling) and face

oedema (face swelling). Hypercalcemia (too much calcium in the blood) and hypercalciuria (too much calcium in the urine), can occur, but this is rare. Worsening of psoriasis, photosensitivity reactions (reacting to sunlight) , pruritus (severe itching), burning sensations, erythema (reddening of the skin) eczema and dermatitis (eczema) have been reported with Daivonex® cream therapy.

Where is the study run from?
CROSS Research Phase I Unit located in Arzo, Switzerland

When is the study starting and how long is it expected to run for?
October 2015 to April 2016

Who is funding the study?
Polichem SA (Switzerland)

Who is the main contact?
Dr Milko Radicioni

Contact information

Type(s)
Scientific

Contact name
Dr Milko Radicioni

Contact details
CROSS Research SA
Phase I Unit
Via FA Giorgioli 14
Arzo
Switzerland
6864

Additional identifiers

Protocol serial number
PM1543

Study information

Scientific Title
Pharmacokinetic profile of calcipotriol after single and 7-day multiple Daivonex® cream application in healthy male volunteers

Study objectives
Description of the pharmacokinetic profile of calcipotriol in plasma after single and multiple dose application of Daivonex® 0.005% cream in healthy male volunteers

Ethics approval required

Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee (Comitato Etico Cantonale), Canton Ticino, Switzerland, 20/11/2015, ref: CE2978

Study design
Single-centre open-label pilot pharmacokinetic study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topical treatment of plaque psoriasis

Interventions
7-day treatment with Daivonex® 0.005% cream (calcipotriol 50 µg/g) twice a day (every 12 hours) topically applied on the back

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Calcipotriol 50 µg/g

Primary outcome(s)
Plasma levels of calcipotriol after single and multiple dose administration of Daivonex® cream will be measured using a fully validated method.
Timepoints:
1. Before the first drug administration
2. 3min, 6min, 9min, 12min, 15min, 20min, 25min, 30min, 40min, 50min, 1h, 1.5h, 2h, 3h, 6h, 9h and 12h after the first dose
3. Before last drug administration
4. 3min, 6min, 9min, 12min, 15min, 20min, 25min, 30min, 40min, 50min, 1h, 1.5h, 2h, 3h, 6h, 9h and 12h after the last dose

Key secondary outcome(s))
1. Adverse events (AEs)
2. Vital signs (BP, HR)
3. ECG
4. Physical examination
5. Laboratory parameters
Measured at screening visit and at the end of the trial (final visit)

Completion date

30/04/2016

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and age: males, 18-55 years old inclusive
3. Body Mass Index: 18.5-30 kg/m2 inclusive
4. Vital signs: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, heart rate 50-90 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
Male

Key exclusion criteria
1. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study; in particular skin damages, tattoos or any abnormal findings in the back
2. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
3. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the investigator considers may affect the outcome of the study
4. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that may interfere with the aim of the study; known or suspected disorders of calcium metabolism associated with hypercalcaemia
5. Medications: medications, including over the counter medications and herbal remedies, calcium, vitamin D or vitamin-like medicines (e.g. calcitriol) for 2 weeks before the start of the study
6. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of

the present study
7. Blood donation: blood donations for 3 months before this study
8. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [>2 drinks/day, defined according to the USDA Dietary Guidelines 2010], caffeine (>5 cups coffee/tea/day) or tobacco abuse (≥10 cigarettes/day)
9. Drug test: positive result at the drug test at screening
10. Alcohol test: positive alcohol breath test at day -1
11.Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study; vegetarians

Date of first enrolment
10/01/2016

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
CROSS Research SA - Phase I Unit
Via F.A. Giorgioli 14
Arzo
Switzerland
6864

Sponsor information

Organisation
Polichem SA

ROR
https://ror.org/05735qy63

Funder(s)

Funder type
Industry

Funder Name

Polichem SA (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes