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A study of the effects of a new drug (DLQ02) for the treatment of psoriasis

Submission date	Recruitment status	[_] Prospectively registered
02/08/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/08/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/04/2024	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Psoriasis is a common skin disorder affecting up to an estimated 3% of the population of the world.

The most prevalent form of psoriasis, psoriasis vulgaris or plaque psoriasis, is characterized by the presence of sharply defined red plaques covered with white scales.

Because of the importance of the inflammatory reaction in the pathogenesis of psoriasis, one of the treatments that can be prescribed is an immunosuppressive drug. This has a strong immunosuppressive effect by reversibly blocking T-cell proliferation. Currently it is only available as an oral solution. The side effect profile includes nausea, hypertension, nephrotoxicity, of which the latter can be irreversible. A topical drug product would therefore have great advantage in the treatment of psoriasis.

A novel topical drug product: DLQ02, with the target to facilitate dermal delivery of the active compound to the target tissues. In this phase I/IIa study the safety, tolerability pharmacodynamics and efficacy of two dose strengths of DLQ02 will be assessed when applied twice a day to one target lesion for four weeks in 36 patients with plaque psoriasis.

Who can participate?

Plaque psoriasis patients of 18 years or older

What does the study involve?

For the study, subjects need to visit the research center of CHDR 13 (part A) and 7 (part B) times in approximately 8 weeks. In part A, for the first 7 days subjects will visit CHDR for approximately 8 hours per day. After that the subjects will return for evaluation and measurements every week.

In part B, subjects will start with the baseline measurements before first dosing, the measurements will be repeated in every weekly visit.

What are the possible benefits and risks of participating?

For new drugs such as DLQ02 not all side effects are known yet. Thus there may be unexpected side effects, for example an allergic or hypersensitivity reaction of the skin. However, since DLQ02 is a topical formulation, the side-effects are expected to be minimal as well.

Where is the study run from?
The centre of Human Drug Research (CHDR) (Netherlands)

When is the study starting and how long is it expected to run for?
October 2021 to September 2023

Who is funding the study?
Dermaliq Therapeutics Inc. (USA)

Who is the main contact
Prof. Robert Rissmann, Principle investigator, clintrials@chdr.nl
Drs. Menthe Bergmans, Project leader, clintrials@chdr.nl

Study website
https://proefpersoon.nl/psoriasis-2041-a

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
202200107113

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DLQ02-001 / CHDR2041

Study information

Scientific Title

A randomized, double-blind, vehicle-controlled trial with safety run-in to assess the safety, tolerability and efficacy of DLQ02, a novel topical calcineurin inhibitor, over four weeks to patients with plaque psoriasis

Acronym
DLQ02

Study objectives
The present study is designed to investigate if:
1. The safety and tolerability of two DLQ02 topical formulations is acceptable to use by plaque psoriasis patients.
2. The systemic exposure of DLQ02
3. There are signs of efficacy of the two DLQ02 topical formulations in plaque psoriasis patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 01/06/2022, Medical Ethics Committee Assen (Dr. Nassaulaan 10, 9401 HK Assen; +31(0) 592 405 871; info@stbebo.nl), ref: CHDR2041
2. Approved 01/06/2022, Stichting Beoordelign Ethiek Biomedisch Onderzoek (Dr. Nassaulaan 10 , Assen, 9401HK, Netherlands; 0592-405871; info@stbebo.nl), ref: NL80977.056.22

Study design
A randomized double-blind vehicle-controlled trial with safety run-in

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://proefpersoon.nl/psoriasis-2041-a

Health condition(s) or problem(s) studied
Treatment for plaque psoriasis patients.

Interventions
This randomized, double-blind, vehicle-controlled trial with safety run-in (part A) will investigate the safety, tolerability and efficacy of DLQ02, over four weeks to patients with plaque psoriasis. 12 patients with plaque psoriasis will complete part A (safety run-in) of the study and 24 plaque psoriasis patients will complete part B of the study.
Each subject will be randomly allocated to receive DLQ02 high dose, low dose, or the matching

vehicle.
In part A the subjects will dose the topical formulation on the psoriasis target lesion for 4 weeks. Furthermore a non-lesional part of the back will be dosed by the physician for the first 7 days.
In part B of the study the subjects will dose with the topical/fluid formulation for 4 weeks on all psoriasis lesions (with a maximum of 2.5% BSA).

Randomization is performed 1:1:1 for the three treatments. The randomization code is generated by an uninvolved statistician using SAS Software and stored in sealed envelopes in a fireproof cabinet.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
DLQ02

Primary outcome measure
1. Target lesions scoring using PASI (part B) and target lesion total signs; erythema, induration and scaling at baseline and study visits (daily visits for one week followed by 1 visit per week for 4 weeks)
2. Patient reported itch as measured using NRS at baseline and at study visits
3. Diary as collected through eDiary at baseline and at study visits
4. Lesion size measured and documentation with 2D photography at baseline and study visits.
5. Lesion size measured using 3D photography at baseline and study visits.
6. Skin morphology using Optical Coherence Tomography at baseline and study visits.
7. Laser speckle contrast imaging at baseline and study visits.
8. Local irritation as measured using local irritation grading score (LIGS) at baseline and at study visits.

Secondary outcome measures
Pharmacokinetic endpoints at baseline and at study visits (daily visits for one week followed by 1 visit per week for 4 weeks):
1. Cutaneous DLQ02 in skin biopsies.
2. Systemic levels of DLQ02.

Pharmacodynamic and efficacy endpoints at baseline and at study visits
1. Severity of psoriasis target lesion using clinical assessments.
2. Percent of patients achieving clinical scores of clear of almost clear.
3. Score of individual symptoms of the target lesion
4. Patient reported outcomes of the target lesion
Target lesion area assessed with:
5. 2D photography
6. 3D photography
7. Optical coherence tomography (OCT)
8. Laser speckle contrast imaging (LSCI)

Overall study start date
25/10/2021

Completion date
08/09/2023

Eligibility

Key inclusion criteria
1. Males or non-pregnant, non-lactating females.
2. At least 18 years of age at time of consent.
3. Have stable psoriatic plaque psoriasis (for 6 months), as confirmed by the patient.
4. Have a maximum (treatable) BSA of 2.5%(only part B).
5. Have a target plaque (area) suitable for treatment 15cm2and ≤100cm2 with a severity defined by TSS score ≥ 4, with at least a clinical score of ≥ 2 for either erythema or induration and ≥1 for the symptom scaling.
6. Able and willing to follow instructions and comply with the study restrictions, including participation in all trial assessments and visits.
7. Provide written informed consent.
8. Willing to refrain from medications for psoriasis according to the wash-out periods.
9. Patients and their partners of childbearing potential must use effective contraception, for the duration of the study and for 3 months after the last dose.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
36 (part A: 12, part B: 24)

Total final enrolment
37

Key exclusion criteria
1. Have any current and/or recurrent clinically significant skin condition which will interfere with the clinical findings of the study as assessed by the investigator
2. Have a current diagnosis of psoriasis other than plaque psoriasis (including guttate psoriasis, psoriasis erythroderma and pustular psoriasis).
3. Use the following psoriasis medications. Wash-out periods are stated below. •Local treatment of plaques with anti-psoriatics (e.g. vitamin D analogs, corticosteroids, retinoids, tacrolimus or other calcineurin inhibitors): 2 weeks prior to baseline•Emollients or scale-softening treatments on target plaques (including salicylic acid): from baseline onwards
4. Have a current systemic treatment with psoriasis medication (e.g. retinoids and immunomodulating drugs such as methotrexate and tacrolimus, CsA or a treatment with biologic.)

5. Begin treatment with systemic or locally acting medications which might counter or influence the study aim (e.g., medications which are known to provoke or aggravate psoriasis including but not limited to antimalarial drugs, beta-blockers [e.g., propanolol], lithium, iodides, angiotensin-converting enzyme inhibitors, nifepidine, indomethacin, ciprofloxacin, and diphenhydramine) prior to baseline (therapy with stable dose is allowed)
6. Begin treatment with CYP3A4 interactive drugs [e.g., miconazole, ketoconazole, erythromycin, clarithromycin, diltiazem, ritonavir, verapamil, grapefruit].
7. Have history of PUVA if >1000 J/cm2or >200 cumulative treatments
8. Have participated in a clinical research trial within 90 days, or 5 half-lives of the investigational product, whichever is greater, prior to baseline visit.
9. Be study site employees, or immediate family members of a study site or sponsor employee.
10. Have prolonged exposure to UV light within two weeks prior to study day 1 or intention to have such exposures during the study.
11. Have a history of drug abuse within the past two years.
12. Regular alcohol consumption in males >21 units per week and females>14 units per week (1 unit approximately 240 ml of beer, 25 ml of 40% spirit or a 125 ml glass of wine), or a history of alcohol abuse within the past two years.
13. Change smoking habits during the 4 weeks prior to study start or during the study; smokers are allowed up to 6 cigarettes per day if smoking is a current habit.
14. Have clinically significant abnormal biochemistry, hematology or urinalysis as judged by the investigator.
15. Have liver function tests (ALT, AST, GGT, ALP) range >2,5X upper limit of normal of each parameter at screening.
16. Have a clinically significant abnormal renal function (including any stage of chronic kidney disease).
17. Have positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab), or human immunodeficiency virus (HIV) results.
18. Have live vaccination during the study or in the 2 weeks before study start.
19. Have vaccination for SARS-CoV-2 within 14 days prior to initial dosing, or planned during the course of the study.
20. Have history of malignancy, except adequately treated non-invasive skin cancer (basal or squamous cell carcinoma).
21. Have clinically significant illness or infection that may, in the opinion of the investigator, contraindicate participation in the trial or interfere with the outcome of the trial in the 4 weeks before the baseline visit and during the trial.
22. Have history of sensitivity to any of the study medications, or components thereof, or a history of drug or other allergy that, in the opinion of the investigator or medical monitor, contraindicates participation.
23. Have clinically significant uncontrolled hypertension as judged by the investigator (stable treatment is allowed).
24. Fail to satisfy the investigator of fitness to participate in the trial for any other reason.
25. Have Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening.

Date of first enrolment
25/07/2022

Date of final enrolment
04/07/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Human Drug Research
Zernikedreef 8
Leiden
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Sponsor information

Organisation
Dermaliq Therapeutics Inc.

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Dermaliq Therapeutics Inc.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date