ISRCTN33393967 https://doi.org/10.1186/ISRCTN33393967

DLQ03 in a wound healing model in patients with atopic dermatitis (eczema)

Submission date
02/08/2022

Recruitment status
No longer recruiting

Registration date
04/08/2022

Overall study status
Completed

Last Edited
05/04/2024

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Skin and soft tissue infections (SSTIs) are one of the most common reasons for patients to seek medical help in dermatology (Bonaparte et al. 2020). Currently there are two main classes of topically applied disinfectant agents which can be applied to living skin or wounds and are able to kill, or reduce the number of microorganisms: disinfectants and antibiotics. There are strong downsides to the use of existing products in both classes of infected wounds (Punjataewakupt et al., 2019). Disinfectants generally kill a broad range of microorganisms and are mostly used for surgical skin sterilization before operations, personal hygiene, and for infection control in wounds. However, disinfectants may be toxic to cells and tissues, strongly limiting their use. Topical antibiotics kill microorganisms with specific targeting and often work on a narrow range of microorganisms. Correct diagnosis of the infection is necessary to select the appropriate treatment as the wrong antibiotic can worsen the disease and allow infection to spread. Further, while topical antibiotics are relatively non-toxic (some are sensitizers), bacterial resistance to antibiotics , especially if the infection is unknown or a broad-spectrum antibiotics is applied, is an increasing problem for both systemic and topical products.

The aim of this study is to assess safety, tolerability and pharmacodynamics of S. aureus eradication of DLQ03 on non-lesional and lesional skin of patients with mild to moderate atopic dermatitis.

Who can participate?
Male/female volunteers with mild to moderate atopic dermatitis (IGA 2 or 3) aged 18 to 65

What does the study involve?
For this study, subjects participating in Part A need to visit the research center 8 times (of which 5 times twice daily) in approximately 4 weeks. Subjects participating in Part B need to visit the research center 16 times in approximately 8 weeks. During these visits, safety checks are performed and swabs are taken to check for S. Aureus load. In Part A all treatment administrations are performed in clinic. In Part B subject will administer at home and at the clinic.

What are the possible benefits and risks of participating?
There are no benefits anticipated in this trial. This is the first time DLQ03 is administered in

humans and not all side effects are known yet. Anticipated side effects are erythema, and itching.

Where is the study run from?
The Centre for Human Drug Research (CHDR) (Netherlands)

When will the study start and how long is it expected to run for?
June 2022 to November 2023

Who is funding the study?
Dermaliq Therapeutics Inc. A pharmaceutical company located in Wilmington, USA.

Who is the main contact?
Laura van der Meulen, Project leader, clintrials@chdr.nl
Robert Rissmann, Principal Investigator, clintrials@chdr.nl

Contact information

Type(s)
Principal investigator

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Clinical Trials Information System (CTIS)
2022-500647-21-00

Protocol serial number
DLQ03-001 / CHDR2153

Study information

Scientific Title
A phase I/II randomized, assessor-blind, vehicle-controlled study to assess the safety, tolerability, and pharmacodynamics of DLQ03 in a wound healing model in patients with mild to moderate atopic dermatitis that are colonized with S. Aureus.

Acronym
DLQ03-001

Study objectives
The present study is designed to investigate if:
1. DLQ03 is safe and well tolerated in patients with mild to moderate atopic dermatitis
2. S. Aureus load is reduced after treatment with DLQ03
3. If epidermal wound healing is affected after prolonged treatment with DLQ03

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/06/2022, Medical Ethics Committee Foundation for the Assessment of Ethics of Biomedical Research (MREC of the foundation BEBO, Dr. Nassaulaan 10, 9401 HK Assen, The Netherlands; +31 592-405871; info@stbebo.nl), ref: CHDR2153
2. Approved 03/06/2022, Stichting Beoordeling Ethiek Biomedisch Onderzoek (Dr. Nassaulaan 10, Assen, 9401 HK, Netherlands; 0592405871; info@stbebo.nl), ref: 2022-500647-21-00

Primary study design
Interventional

Study design
A phase I/II randomized assessor-blind vehicle-controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of skin and soft tissue infections

Interventions
This phase I/II randomized, assessor-blind, vehicle-controlled study will assess the safety, tolerability, and pharmacodynamics of DLQ03 in a wound healing model in patients with mild to moderate atopic dermatitis that are colonized with S. aureus.

All treatments are packaged similarly to ensure double blind randomization. Based on the assigned treatment, each subject will be randomly allocated to receive a single/multiple dose in either part A of part B of the study. Each subject will receive one of the following treatments:
- DLQ03 high dose
- DLQ03 low dose
- Vehicle control

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.

Administration is performed topically on allocated target areas.
Participants are followed up daily for one week.

Intervention Type
Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)
DLQ03

Primary outcome(s)
1. Staph. Aureus load measured using Swabs at baseline and at study visits (daily for one week).
2. Wound size measured using calliper and 3D imaging at baseline and at study visits
3. Suction blister fluid at baseline and at study visits
4. Laser Speckle Contract Imaging at baseline and at study visits
5. Transepidermal water loss measured with TEWL at baseline and at study visits
6. Thermography using infrared thermography at baseline and at study visits.
7. Skin morphology using Optical coherence tomography at baseline and at study visits

Key secondary outcome(s)
1. Local irritation as measured using local irritation grading score (LIGS) at baseline and at study visits.
2. Target lesions scoring using oSCORAD, EASI, target lesion total signs and symptoms and surface area at baseline and study visits
3. Patient reported itch as measured using NRS at baseline and at study visits
4. Diary as collected through eDiary at baseline and at study visits

Completion date
21/11/2023

Eligibility

Key inclusion criteria
1. Male and female subjects with mild to moderate AD (IGA 2 or 3) 18 to 65 years of age, inclusive. The health status is verified by absence of evidence of any clinically significant active or uncontrolled chronic disease other than AD that potentially may influence the adherence to the study and/or assessments in the study, following a detailed medical history and a complete physical examination including vital signs, 12-lead ECG, hematology, blood chemistry, virology, and urinalysis.
2. Diagnosed with AD according to the Hannifin criteria (Hannifin 1980).
3. Suitable target lesion defined as an eczema lesion of at least 0.5% BSA (excluding the face) at screening and baseline day 1 for part A and 2 suitable target lesions defined as two eczema lesions of at least 0.5% BSA (excluding the face) at screening and baseline day 1 for part B. In Part B the location of one of the lesions must be such that suction blisters can be drawn on the lesion.
4. Target lesion is cultured positive for S. aureus on two consecutive occasions during the screening period:
5. Maximum 15% body surface area (BSA) affected at screening and baseline (day 1).
6. Willing to refrain from washing the target lesion(s) at least 6 but preferably 12 hours before every study visit.
7. Subjects and their partners of childbearing potential must use effective contraception, for the duration of the study and for 3 months after the last dose.
8. Able to participate and willing to give written informed consent and to comply with the study restrictions.
9. Has the ability to communicate well with the Investigator in the Dutch language.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. 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. Ongoing use of prohibited atopic dermatitis treatments. Washout periods prior to baseline (first dose of the study drug) are as follows:
2.1. Target lesions only: Any topical medication (prescription or over-the-counter [OTC]) for 14 days)
2.2. Cyclosporine/oral steroids/azathioprine/mycophenolate mofetil/other systemic AD treatments: 4 weeks
2.3. Phototherapy: 3 weeks
2.4. Biologics: 5 half-lives of the drug
2.5. Systemic antibiotics: 14 days
3. Tanning due to sunbathing, excessive sun exposure or a tanning booth within 3 weeks of enrollment and/or not willing to refrain from these during the study.
4. Part B only: Subject has a Fitzpatrick's Skin Phototype ≥ 4.
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 atopic dermatitis).
6. Known hypersensitivity to the F6H8 eyedrop.
7. Pregnant, a positive pregnancy test, intending to become pregnant, or breastfeeding.
8. Participation in an investigational drug or device study within 3 months prior to screening or more than 4 times a year.
9. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening.
10. A positive drug and/or alcohol test at screening (rescreening is allowed).
11. Have positive hepatitis B surface antigen (HBsAg), hepatitis C virus antibody (HCV Ab), or human immunodeficiency virus (HIV) results.
12. Any disease associated with immune system impairment, including auto-immune diseases, HIV, and transplantation patients.
13. Any disease associated with thyroid dysfunction or impaired renal function.
14. Have history of malignancy, except adequately treated non-invasive skin cancer (basal or squamous cell carcinoma).
15. History of pathological scar formation (keloid, hypertrophic scars)
16. Any form of body modification hindering study assessments (e.g., tattoos, piercings,

implants)
17. 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.
18. Requirement of immunosuppressive or immunomodulatory medication within 30 days prior to enrollment or planned to use during the study
19. Have used Evotears®, Evotears® Omega, Novatears® or Novatears® Omega one week before Day 1 or plan to use it during the course of the trial

Date of first enrolment
08/08/2022

Date of final enrolment
16/10/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Centre for Human Drug Research
Zernikedreef 8
Leiden
Netherlands
2333 CL

Sponsor information

Organisation
Dermaliq Therapeutics Inc.

Funder(s)

Funder type
Industry

Funder Name
Dermaliq Therapeutics Inc.

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes