

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

<b>Submission date</b> 02/08/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/04/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:clintrials@chdr.nl)

Robert Rissmann, Principal Investigator, [clintrials@chdr.nl](mailto:clintrials@chdr.nl)

### **Study website**

<https://proefpersoon.nl>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Prof Robert Rissmann

### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

2022-500647-21-00

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

**Study design**

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

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

**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 measure**

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 Contrast 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

### **Secondary outcome measures**

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

### **Overall study start date**

03/06/2022

### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

27

**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  $\geq 4$ .
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**

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Leiden  
Netherlands  
2333 CL

## Sponsor information

### Organisation

DermalIQ Therapeutics Inc.

### Sponsor details

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erowold@dermalIQ.com

### Sponsor type

Industry

### Website

<https://dermalIQ.com>

## 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

30/09/2024

### 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