A randomized, double-blind, placebo controlled, single center study to assess the efficacy and pharmacodynamics of Gladskin eczema cream BID in patients with mild to moderate atopic dermatitis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24034

Source
NTR

Brief title
CHDR1931

Health condition

Eczema (atopic dermatitis)

Sponsors and support

Primary sponsor: Micreos Human Health
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Efficacy endpoint
- Eczema Area and Severity Index (EASI) score at Day 15

Secondary outcome

Tolerability / safety endpoints
- Adverse events (AE) will be collected throughout the study, at every study visit.
Pharmacodynamic endpoints (at the protocol indicated timepoints)
- Multispectral imaging (erythema and roughness of target lesion)
- Laser speckle contrast imaging (blood flow of target lesion)
- Microbiome of skin lesions (of target lesion and non-lesional skin)
- Bacterial colonization of skin lesions (S. aureus cultures of target lesion and non-lesional skin)
- Local (biopsy) biomarkers may comprise, but are not limited to: IL-13, IL-4, IL-5, IL-33, TSLP, IL-31, IL-22, eotaxin
- Transepidermal water loss of lesional and non-lesional skin

Efficacy endpoints (at the protocol indicated timepoints)
- Clinical assessment using oSCORAD, EASI, IGA
- Target lesion oSCORAD and Total Signs and Symptoms (TSS)
- Patient-reported itch (daily Numerical Rating Scale (NRS) by ediary(app)) and Patient Oriented Eczema Measure (POEM)
- Dermatology Life Quality Index (DLQI)
- Standardized total body clinical photography
- Electronic diary for medical device compliance and use of escape medication

Study description

Background summary

Staphylococcus aureus is an important player regarding dysbiosis in AD. Colonization with this pathogen and a lower general microbial diversity is apparent in approximately 70-90% of the AD patients (Totte et al., 2016). Based on this hypothesis, the microbiome and especially S. aureus might be a target for novel therapies (Geoghegan et al., 2018, Nakatsuji et al., 2017). A topical treatment targeting the perturbed microbiome is Gladskin Eczema Cream. Gladskin is a topical cream registered as medical device class I, with Staphefekt SA.100, a recombinant chimeric endolysin, as active ingredient. Endolysins are bacteria-killing enzymes that originate from bacteriophages. Gladskin specifically targets Staphylococcus aureus, leaving the other bacteria unharmed. It is currently on the market as medical device for skin conditions with an infectious component, e.g. acne vulgaris, rosacea and atopic dermatitis. Questionnaire studies, both prospective and retrospective, indicate the potential for using Gladskin in patients with eczema. However, no randomized controlled clinical study has been performed to explore the potential of Gladskin as monotherapy in patients with mild to moderate atopic dermatitis.

This study will assess the efficacy, safety and pharmacodynamic effects of Gladskin in patients with mild to moderate atopic dermatitis. After informed consent and screening a wash-out phase of up to 28 days is allowed for cessation of any non-allowed concomitant medications. At Day 1, treatment with Gladskin BID daily for 14 days is initiated. Study visits are planned at Day 8 and Day 15. A follow-up visit is done at Day 22.

Study objective

Gladskin cream will decrease the presence of Staphylococcus aureus and thereby will improve the clinical picture of the eczema patients.

Study design

Screening, Day 1, Day 8, Day 15 and Day 22

Intervention

Gladskin eczema cream, BID for 14 days

Contacts

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Eligibility criteria

Inclusion criteria

For enrollment of subjects the following criteria must be met:
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 following a detailed medical history and a complete physical examination

2. Diagnosed with AD according to the Hanifin criteria
3. EASI ≥4
4. Suitable target lesion defined as an eczema lesion of at least 1% BSA (preferably the antecubital fossa) with at least mild erythema and mild induration
5. ≥5% body surface area (BSA) affected at screening and baseline
6. Willing to not wash the target lesion 12 hours before every study visit
7. Willing to use microbiome friendly wash solution and refrain from other products for washing from screening until end-of-study
8. Able to participate and willing to give written informed consent, and to comply with the study restrictions
9. Has sufficient Dutch language skills to be able to communicate well with the Investigator, understand the informed consent and complete questionnaires and e-diary.

Exclusion criteria

1. Any current and / or recurrent clinically significant skin condition other than AD
2. Ongoing use of prohibited atopic dermatitis treatments. Washout periods prior to baseline (first dose of the study medical device) are as follows:
a. Any topical medication (prescription or over-the-counter [OTC]): 14 days. Continued use of emollients during wash-out is allowed.
b. Cyclosporine/oral steroids/azathioprine/mycophenolate mofetil/other systemic AD treatments: 4 weeks
c. Phototherapy: 3 weeks
d. Biologics: 5 half-lives of the drug
e. Systemic antibiotics: 14 days
3. Tanning due to sunbathing, excessive sun exposure or a tanning booth within 3 weeks of enrollment
4. Known hypersensitivity to the compound or excipients of the compound
5. Pregnant, a positive pregnancy test, intending to become pregnant, or breastfeeding;
6. Participation in an investigational drug or device study within 3 months prior to screening or more than 4 times (including this study) a year
7. Any (medical) condition that would, in the opinion of the investigator, potentially compromise the safety or compliance of the patient or may preclude the patient’s successful completion of the clinical trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.A.

Ethics review

Positive opinion

Date:	23-12-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49563
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8250
CCMO	NL71660.056.19
OMON	NL-OMON49563

Study results

Summary results
N.A.