The effect of Gladskin on the disease severity and the skin microbiome, including Staphylococcus aureus, in patients with atopic dermatitis.

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The goal of this study is to evaluate the effect of Gladskin on usage of topical corticosteroids in patients with atopic dermatitis. Secondary goals are to retrieve information about the effect of Gladskin on clinical symptoms, quality of life,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON46056

Source
ToetsingOnline

Brief title
The effect of Gladskin on atopic dermatitis and the skin microbiome.

Condition

- Bacterial infectious disorders
- Skin and subcutaneous tissue disorders NEC

Synonym
atopic dermititis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Micreos Human Health BV

Intervention

Keyword: Atopic dermatitis, Microbiome, Staphefekt, Staphylococcus aureus

Outcome measures

Primary outcome

Difference in number of days/week corticosteroid use between verum and placebo group over 12 weeks.

Secondary outcome

1. Efficacy:

- Difference in mean grams/week topical corticosteroid use between verum and placebo group over 12 and 20 weeks.

- Proportion of patients with AD who indicate to have used less corticosteroids at week 2 and 12, as compared to baseline and at week 20 as compared to the 12 week treatment period (appendix 8).

- Change in Eczema Area and Severity Index (EASI) from baseline to week 2, 6, 12 and 20

- Change in Patient Oriented Eczema Measure (POEM) from baseline to week 2, 6, 12 and 20

- Proportion of patients with a reduction from baseline of 2 or more points of Investigators global assessment (IGA) at week 2, 6 and week 12

- Change in IGA from baseline to week 2, 6 and 12 and week 20

- Change in Pruritus Numerical Rating Scale (Pruritus NRS) from baseline to

week 2, week 6 and week 12 and week 20

- Proportion of patients with a change in Pruritus numerical Rating Scale (Pruritus NRS) form baseline to week 2, week 12 and week 20.

- Mean time to flare from baseline through week 12 and from week 12 through week 20. Flare is defined is an exacerbation that requires the need of any stronger topical therapy, an increase in dosage of the topical therapy or the need of a systemic therapy.

2. Quality of Life:

- Change in Skindex-29 score from baseline to week 12 and week 20.

3. The effect of Gladskin on the dynamics of S. aureus and on other microorganisms on skin/mucosa:

- Proportion of patients with a reduction of S. aureus from baseline to measurement 1 (0,5hour after baseline) as determined by semi quantitative culture

- Proportion of patient with a > 1 log reduction of S. aureus from the lowest measurement (visit 1 or visit 2a) to week 2 and week 12 as determined by quantitative QPCR

- Change in relative abundance of bacteria: determined by 16s rRNA sequencing

4. Safety and tolerability of Gladskin:

- Incidence of (serious) adverse device events from baseline through the end of the study.

Study description

Background summary

Staphylococcus aureus (S. aureus) is both a commensal and a pathogenic organism. Carriage of S. aureus is not harmful per se, however the bacteria is responsible for the vast majority of skin infections, such as impetigo and infection of wounds. Also colonization with S. aureus is related to atopic dermatitis. Increasing multidrug resistance of S. aureus points out the need for development of alternative treatment options. Gladskin is a product for topical use. The proprietary enzyme in the Gladskin products is called Staphefekt. Staphefekt specifically lyses the cell wall of S. aureus. In vitro results showed that Staphefekt kills S. aureus, leaving the commensal flora intact. Gladskin might decrease S. aureus colonization of the skin and consequently decrease occurrence of and/or symptoms of S. aureus related disease.

Study objective

The goal of this study is to evaluate the effect of Gladskin on usage of topical corticosteroids in patients with atopic dermatitis. Secondary goals are to retrieve information about the effect of Gladskin on clinical symptoms, quality of life, growth characteristics of S. aureus and the further microbiome.

Study design

A multi center intervention study with a placebo controlled, double blind and randomized design. All patients that fulfill the criteria for in- and exclusion will be randomized in a 1:1 fashion to topical corticosteroid treatment (triamcinolone acetonide 0.1%) combined with Gladskin cream or topical corticosteroid treatment (triamcinolone acetonide 0.1%) combined with a placebo.

Intervention

Patients with atopic dermatitis of moderate or severe severity will be screened and characterized. Swabs will be collected of the nares, the pharynx and the lesional skin and patient characteristics will be evaluated using a questionnaire addressing e.g. history of skin disease. All patients that fulfill the criteria for in- and exclusion will be randomized in a 1:1 fashion to topical corticosteroid treatment (triamcinolone acetonide 0.1%) combined with Gladskin cream or topical corticosteroid treatment (triamcinolone acetonide 0.1%) combined with a placebo. Gladskin/Placebo will be used on the complete skin surface twice daily during 12 weeks. Topical corticosteroid use will be evaluated 2, 6, 12 and 20 weeks after start of the intervention. Swabs of the skin, nose and throat will be collected at baseline, week 2, 12 and 20.

Study burden and risks

Benefit: Participation in this study might result in individual benefit for the patient, as Gladskin might reduce S. aureus load on the skin. Flares in patients with eczema are associated with higher loads of S. aureus.
Burden: The study includes 6 visits within 22 weeks. Visits will take approximately 30 minutes. (Visit 2 will take approximately 1 hour). Screening for S. aureus is performed using swabs, a non-invasive method.
Risks: The risk of using Gladskin is low. Since endolysins are proteins, they are inherently non-toxic. Theoretically toxicity can occur when in the purification process of the lysins a toxic substance of the host bacteria is co-purified. Staphefekt is tested on purity (host cell contamination and endotoxin levels) according to European regulations. Staphefekt is a large size protein molecule (>50kDa) and will not penetrate or pass intact skin. In animal testing with other endolysins (not Staphefekt) no adverse side effects were seen. There is a possibility of a contact allergic reaction to other basic components (cera cetomacrogol) of the product or the swab solution (tween).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Atopic dermatitis of moderate severity. Defined by EASI score of 7 to 50 performed by the researcher at visit 1.
2. > 18 years old
3. Topical corticosteroid use (of any type).
4. Able to read patient information and provide informed consent

Exclusion criteria

1. Use of systemic antibiotics or corticosteroids within the last 2 months
2. Use of Methotrexate or oral immunosuppressive agents in the last 3 months
3. Use of topical antibiotics in the previous 7 days
4. Use light therapy in the previous 3 months.
5. Use of Gladskin in the previous 7 days
6. Allergy to components of the study drug
7. Clinically infected atopic dermatitis
8. Existence of another skin condition, such as folliculitis psoriasis that could interfere with the assessment of the eczema severity.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2016
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Gladskin
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-06-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02840955
CCMO	NL57362.078.16