The effect of Staphefekt on the skin microbiome, including Staphylococcus aureus, in patients with atopic dermatitis.

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To retrieve (in vivo) data about the effect of Staphefekt on the microbiome, including Staphylococcus aureus, and on disease severity in patients with atopic dermatitis.

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

Summary

ID

NL-OMON40588

Source
ToetsingOnline

Brief title
The effect of Staphefekt on 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: Micreos

Source(s) of monetary or material Support: Micreos Human Health BV

Intervention

Keyword: Microbiome, Staphefekt, Staphylococcus aureus

Outcome measures

Primary outcome

1. The dynamics of S. aureus after application of Staphefekt on skin/mucosa

2. Effect of Staphefekt on disease severity of atopic dermatitis (compared to placebo)

Secondary outcome

1. Effect of Staphefekt on other microorganisms on skin/mucosa

2. Possible side-effects of Staphefekt

Study description

Background summary

Staphylococcus aureus (S. aureus) is both a commensal and a pathogenic organism. Carriage of S. aureus is not harmfull per se, however there is a risk of autoinfection. 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 for bacterial infections. Gladskin is a product for topical use. The proprietary enzyme in the Gladskin products is called Staphefekt. Staphefect specifically lyses the cell membrane of Staphylococcus aureus. In vitro results showed that Staphefekt kills S. aureus, leaving the commensal flora intact. Staphefekt might decrease S. aureus colonisation of the skin and consequently decrease occurrence of and/or symptoms of S. aureus related disease.

Study objective

To retrieve (in vivo) data about the effect of Staphefekt on the microbiome, including Staphylococcus aureus, and on disease severity in patients with

atopic dermatitis.

Study design

A single centre intervention study with a placebo controlled, double blind and randomized design.

Intervention

30 patients are recruited and characterized. Characterization of patients includes (1) determination of S. aureus colonization status by screening the nares, the pharynx and the lesional skin (preferably left and right anticubital folds) and (2) evaluation of patient characteristics using a questionnaire addressing e.g. history of skin disease. Of the 30 patients, 16 colonized patients and 6 non-colonized patients will be included in the study. The intervention includes application of Staphefekt or placebo in the nose and on the skin lesions (anticubital folds), twice daily during 3 weeks. Microbiome of the nose and skin and disease severity will be measured at baseline, right after the first application and one and three weeks later. Isolation of S. aureus and other skin bacteria is performed by culture, QPCR and 16S rRNA sequencing. Disease severity will be assessed using the EASI and Self Administrated-EASI. Seven days after application of Staphefekt side-effects are evaluated through a questionnaire.

Study burden and risks

Risks: Based on current literature, internal assessments and evaluations by ETH (Eidgenössische Technische Hochschule, Zurich, Switzerland) it can be concluded that Staphefekt is safe for its targeted applications on the skin. This is evaluated externally by TNO. TNO concludes that endolysins can be used safe as medical device in the treatment of (MR)SA on the skin. In animal testing no adverse side effects of lysins are seen. There is a possibility of a contact allergic reaction to other basic components (cera cetomacrogol) of the product or the swab solution (tween).
Benefit: Participation in this study might result in individual benefit for the patient, as Staphefekt might reduce S. aureus load on the skin/mucosa. Flares in patients with eczema are associated with higher loads of S. aureus.
Burdening: The study includes 5 visits within 5 weeks of time. During the first visit (30 minutes) patients are screened on in- and exclusion criteria, informed consent is obtained, patient characteristics are evaluated and skin and nasal swabs are taken. The second visit (10 min) includes a skin and nasal swab. During the third visit the researcher assesses the patients skin, the patients fills in a questionnaire and swabs are taken from the skin (before application of Gladskin, 1 hour after application and 6 hours after application). The fourth and fifth visit (30 minutes) includes assessment of disease severity and performing a skin- and nasal swab. Screening for S. aureus

is performed using swabs, a non-invasive method. Psychological discomfort is kept to a minimum by letting subjects perform the perineum swab themselves (after verbal instruction).

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 performed by the researcher at time of recruitment.
2. > 18 years old
3. At least 2 lesions at similar body sites (similar habitat) suitable for sampling
4. Colonisation of the nares and skin (2 lesions) with S. aureus, defined as having 2 positive cultures with an interval of one week.
5. Loads of Staphylococcus aureus are high enough for quantitative analysis (15-300 colony

forming units per plate). Detection limits are based on ISO standards (4833:2003 and 6888-1:1999).

Exclusion criteria

1. Use of systemic antibiotics or corticosteroids within the last 6 months
2. Use of Methotrexate or immunosuppressive agents
3. Irregular intermittent use of topical or inhaled steroids within the last 6 months
4. Use of topical antibiotics in the previous 7 days
5. Use of Gladskin within the previous 4 weeks
6. Allergy to components of the study drug

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:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	16
Type:	Anticipated

Medical products/devices used

Generic name:	Gladskin
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-10-2014
Application type:	First submission
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
CCMO	NL47287.078.13