The effect of Gladskin (Staphefekt) treatment on the severity of skin symptoms in patients with Netherton syndrome

No registrations found.

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

Summary

ID

NL-OMON26178

Source
NTR

Brief title
NS-study

Health condition

- Netherton syndrome
- Staphylococcus aureus
- Microbiome

Sponsors and support

Primary sponsor: Erasmus University Medical Center Rotterdam
Source(s) of monetary or material Support: The department of Dermatology of the Erasmus University Medical Center Rotterdam received an unrestricted grant of Micreos Human Health, the Netherlands.

Intervention

Outcome measures

Primary outcome

Patient reported disease severity score using the Patient Global Assessment (PGA)

Secondary outcome

- Patient reported disease severity scores (prutitis NRS, pain NRS, desquamation NRS, erythema NRS, sleep NRS)

- Visual index for Ichthyosis severity (VIIS)

- Staphylococcus aureus load and other microorganisms on skin and nose mucosa measured by DNA based methods and culture

- Safety and tolerability of Gladskin

Study description

Background summary

Netherton syndrome is a rare autosomal recessive form of severe ichthyosis caused by mutations in the serine protease inhibitor Kazal type 5 (SPINK5). The disease is characterized by ichthyosis linearis circumflexa, erythematous, dry and scaling skin lesions typical for NS. Colonization of the skin and mucosa with Staphylococcus aureus might worsen the skin symptoms of NS and causes recurrent skin infections in these patients. Antibiotics are often used to treat these skin symptoms and infections. Because of common side effects and increasing multidrug resistance of S. aureus, NS patients might benefit from alternative treatment. Gladskin is a product for topical use, the proprietary enzyme in the Gladskin products is called Staphefekt SA.100 (Staphefekt). Staphefekt is an endolysin that specifically lyses the cell membrane of S. aureus. In vitro results showed that Staphefekt kills S. aureus, including methicillin resistant S. aureus. Treatment with Gladskin might decrease S. aureus on the skin and consequently decrease symptoms and severity of S. aureus related disease.

Study objective

- A decrease in Staphylococcus aureus colonization on skin

- A decrease in skin symptoms (including erythema, pain, desquamations, pruritis infections)

Study design

TO (week 0): enrollment

T1 (week 2) : start of intervention

T2 (week 10): end of intervention

Intervention

The intervention includes Gladskin (Staphefekt) gel application

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- 18 years of age or above

- Having a diagnosis of Netherton syndrome

- Able to read patient information, fill out online questionnaires and provide informed consent

Exclusion criteria

- Systemic antibiotics within the previous 4 weeks

- Topical antibiotics within the previous 7 days

- Gladskin within the previous 7 days

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	11
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-12-2018
Application type:	First submission

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
NTR-new	NL7431

Register	ID
NTR-old	NTR7673
Other	NL63546.078.18 : MEC-2018-130

Study results