

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

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- A decrease in Staphylococcus aureus colonization on skin - A decrease in skin symptoms (including erythema, pain, desquamations, pruritis infections)

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26178

Bron

Nationaal Trial Register

Verkorte titel

NS-study

Aandoening

- Netherton syndrome
- Staphylococcus aureus
- Microbiome

Ondersteuning

Primaire sponsor: Erasmus University Medical Center Rotterdam

Overige ondersteuning: The department of Dermatology of the Erasmus University Medical Center Rotterdam received an unrestricted grant of Micreos Human Health, the Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- A decrease in *Staphylococcus aureus* colonization on skin
- A decrease in skin symptoms (including erythema, pain, desquamations, pruritis infections)

Onderzoeksopzet

TO (week 0): enrollment

T1 (week 2) : start of intervention

T2 (week 10): end of intervention

Onderzoeksproduct en/of interventie

The intervention includes Gladskin (Staphefekt) gel application

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Systemic antibiotics within the previous 4 weeks
- Topical antibiotics within the previous 7 days
- Gladskin within the previous 7 days

Onderzoeksopzet

Opzet

Type: Interventie onderzoek
Onderzoeksmodel: Parallel

Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	11
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-12-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7431
NTR-old	NTR7673
Ander register	NL63546.078.18 : MEC-2018-130

Resultaten