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.

Gepubliceerd: 23-12-2019 Laatst bijgewerkt: 15-05-2024

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

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

Samenvatting

ID

NL-OMON24034

Bron
NTR

Verkorte titel
CHDR1931

Aandoening

Eczema (atopic dermatitis)

Ondersteuning

Primaire sponsor: Micreos Human Health
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Gladskin eczema cream, BID for 14 days

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-12-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	23-12-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49563
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N.A.