

Antibacterial clothing study

Gepubliceerd: 28-08-2019 Laatste bijgewerkt: 18-08-2022

Antimicrobial therapeutic clothing are more effective in reducing the severity of atopic dermatitis than non-antimicrobial therapeutic clothing

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

Samenvatting

ID

NL-OMON25728

Bron

NTR

Verkorte titel

ABC study

Aandoening

Atopic dermatitis

Ondersteuning

Primaire sponsor: Erasmus MC

Overige ondersteuning: ZonMW, BAP medical, D&M, DeclaCare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in disease severity measured by the EASI by between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months

Toelichting onderzoek

Achtergrond van het onderzoek

Atopic dermatitis (AD) is a chronic inflammatory skin disease that affects 10% to 20% of children and between 2% and 15% of the adults in Western Europe. Since 2000 therapeutic clothing or functional textiles based on silver or chitosan as antibacterial agents were introduced as therapeutics of AD. These agents aim to reduce skin colonization with *Staphylococcus (S.) aureus*. *S. aureus* induces further dysregulation of the inflammatory process and increased colonization with *S. aureus* is correlated with increased AD severity. The antimicrobial effects of silver and chitosan have been demonstrated before. Based on the theoretical mode of action and clinical experience, we assume a higher effectiveness of antimicrobial therapeutic clothing compared to control therapeutic clothing on reducing AD severity. The goal of this study is to assess the effectiveness of antibacterial clothing based on silver or chitosan on the doctor-reported AD severity in patients with moderate to severe AD. Secondary goals are to retrieve information about the effect of antimicrobial clothing on clinical symptoms, quality of life, *S. aureus* colonization, AD medication use and the satisfaction regarding the clothing.

Doel van het onderzoek

Antimicrobial therapeutic clothing are more effective in reducing the severity of atopic dermatitis than non-antimicrobial therapeutic clothing

Onderzoeksopzet

T= -2 weeks, baseline, 1 month, 3 months, 6 months and 12 months

Onderzoeksproduct en/of interventie

The control group will receive non-antimicrobial therapeutic clothing.

The chitosan group will receive antimicrobial therapeutic clothing based on chitosan

The silver group will receive antimicrobial therapeutic clothing based on silver

All therapeutic clothing is to be worn at night during the 12-month intervention period and if needed during the day

Contactpersonen

Publiek

ErasmusMC

Suzanne Pasmans

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- AD diagnosed according to the criteria of Williams (Williams 1994);
- Age 0 - 80 years;
- AD severity according to EASI at $t = 0 > 6.0$.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Treatment with oral antibiotics until 1 month before inclusion;
- Treatment with topical antibiotics until 1 week before inclusion;
- Treatment with systemic immunosuppressive agents or light therapy until 1 month before inclusion;
- Treatment with (antibacterial) therapeutic clothing until 1 month before inclusion;
- Impaired kidney function (anamnestic assessed)
- Pregnancy or pregnancy wish during study (anamnestic assessed)
- Hypersensitivity to silver (anamnestic assessed)
- Evidence of past non-compliance to treatments or appointments.

Onderzoekopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	165
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:	28-08-2019
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	NL7982

Register

Ander register

ID

METC Rotterdam : MEC-2018-1609

Resultaten

Samenvatting resultaten

N/A