Antibacterial clothing study

No registrations found.

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

Summary

ID

NL-OMON25728

Source
NTR

Brief title
ABC study

Health condition

Atopic dermatitis

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMW, BAP medical, D&M, DeclaCare

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Difference in corticosteroid ointment or cream between the clothing without antimicrobial

agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) assessed in the periods, 0 - 1 months, 1 - 3 months, 3 - 6 months, 6 - 12 months
- Difference in investigator global assessment between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) assessed in the periods, 0 - 1 months, 1 - 3 months, 3 - 6 months, 6 - 12 months
- Difference in patient global assessment between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) assessed in the periods, 0 - 1 months, 1 - 3 months, 3 - 6 months, 6 - 12 months
- Difference in global assessment of degree of impetiginisation (pustules, oozing, crust formation) of dermatitis between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups), expressed as 0 – no impetiginisation, 1 – sporadic impetiginisation, 2 – mild impetiginisation, 3 – moderate impetiginisation, 4 – severe impetiginisation
- Difference in S. aureus colonization (semi-quantitative culture) between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months;
- Difference in POEM or POEM for proxy completion in the case of children up to 10 years of age by their parents between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 monhts
- Difference in IDLQI<4 years, CDLQI < 16 years or DLQI ≥ 16 years between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in DFI in patients <18 years between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months.
- Difference in FDLQI of parents in patients <18 years and partners in patients >18 years between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months.
- Difference in TAPQQOL in patients <6 years, TACQOL in patients <16 and TAAQOL in patients >16, between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months.
- Difference in degree of itching, expressed on a visual analogue scale (0-100 mm), between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in degree of sleep disturbance, expressed on a VAS (0-100 mm), between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
Difference in degree of pain, expressed on a VAS (0-100 mm), between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in degree of bother, expressed on a visual analogue scale (0-100 mm), between

the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in degree of satisfaction and compliance regarding the clothing medication diary including use of emollients between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in control of atopic dermatitis (bases on RECAP questionnaire) between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in antibiotics and topical treatment between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months
- Difference in the QALYs based on EuroQol questionnaire between the clothing without antimicrobial agents (control group) and microbial growth reducing/ antimicrobial clothing based on chitosan or silver (intervention groups) over 12 months

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2020
Enrollment:	165
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	28-08-2019
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	NL7982
Other	METC Rotterdam : MEC-2018-1609

Study results

Summary results
N/A