Pragmatic randomized controlled multi center trial comparing the effectiveness of antibacterial therapeutic clothing based on silver or chitosan as compared with non-antibacterial therapeutic clothing in patients with moderate to severe atopic dermatitis (AD)

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON55834

Source
ToetsingOnline

Brief title
ABC study

Condition

- Epidermal and dermal conditions

Synonym
Atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,BAP Medical,BAP Medical;D&M and DeclaCare,D&M

Intervention

Keyword: Antibacterial clothing, Atopic dermatitis, Staphylococcus aureus, therapeutic clothing

Outcome measures

Primary outcome

To assess the effectiveness of antibacterial clothing based on silver or

chitosan on the doctor-reported AD severity (Eczema Area and Severity Index,

EASI) in patients with moderate to severe AD.

Secondary outcome

To evaluate the effect of antimicrobial clothing based on silver or chitosan in

patients with AD on:

Disease severity measured by the

- Patient Oriented Eczema Measure (POEM) or POEM for proxy completion in case

of children up to 10 years of age by parents;

- Degree of itching (VAS);

- Degree of sleep disturbance (VAS);

- Degree of infection.

- IGA (investigator Global Assessment)

- RECAP

Amount and potency of topical corticosteroid use;

Use of emollients and antibiotics;

S. aureus colonization;

Quality of life measured by the

- Infants Dermatology Life Quality Index (IDLQI), Children's Dermatology Life

Quality Index (CDLQI) < 16 years of age. Dermatology Life Quality Index (DLQI)

* 16 years of age, Family Dermatology Life Quality Index (FDLQI) and Dermatitis

Family Impact (DFI)

- Euroqol questionnaire.

- TAPQOL,TACQOL, TAAQOL

Adherence and Satisfaction regarding the clothing

Silver excretion in urine

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.Therapeutic clothing has been used for decades as part of AD treatment. Historically, cotton bandages were used to cover the affected skin. This provides a fixation of creams and ointments, thereby possibly enhancing their action. It also protects the skin from further damage through scratching and irritating factors (Ring 2012). Since 2000 therapeutic clothing or functional textiles based on silver or chitosan as antibacterial agents were introduced. 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.

Study objective

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 design

A multi-center, double-blind, randomized controlled trial. Patients will be randomized in a 1:1:1 fashion to either therapeutic clothing without antimicrobial agents, antimicrobial therapeutic clothing based on chitosan or antimicrobial clothing based on silver for 12 months.

Intervention

Patients are randomized into one of three intervention groups. Group A will receive therapeutic clothing without antimicrobial agents (control group), group B will receive antimicrobial therapeutic clothing based on chitosan, and group C will receive antimicrobial clothing based on silver. All therapeutic clothing is to be worn at night most times during the 12-month intervention period. It is also possible to wear the clothing during the day if necessary. Usual care including application of emollients, corticosteroid ointments or creams only if needed and/or antihistamines is continued, with standardized steroid ointments and treatment regimens for comparability purposes.

Study burden and risks

No risks expected

Contacts

Public
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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

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
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-03-2020
Enrollment:	165
Type:	Actual

Medical products/devices used

Generic name:	therapeutic clothing
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-04-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	19-03-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	09-02-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL67981.078.18