

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Epidermal and dermal conditions
<b>Study type</b>	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**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80  
Rotterdam 3015 CN  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80  
Rotterdam 3015 CN  
NL

## 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  $t \leq 0$ :  $> 6.0$

### 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