Antimicrobial effect and penetration of silver from silver garments

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON38442

Source
ToetsingOnline

Brief title
Silver-containing textiles and the skin

Condition

- Epidermal and dermal conditions

Synonym
Atopic Dermatitis / Atopic Eczema

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NWO-FES,Argentum

Intervention

Keyword: Antimicrobial, Atopic Dermatitis, Dermal absorption, Silver

Outcome measures

Primary outcome

The following parameters will be measured:

1. Total concentration and size of Ag particles in different layers of the

stratum corneum harvested by adhesive tape stripping.

2. Concentration of inflammatory mediators (including IL-1α, Il-1RA, and IL-8)

in the stratum corneum harvested by adhesive tape stripping

3. Concentration of Ag in urine

4. Density of Staphylococcus aureus on the skin surface, sampled by using

cotton swabs.

Secondary outcome

not applicable

Study description

Background summary

Silver shows a good antibacterial property. Thus, there is a growing interest to develop various silver releasing products, such as clothes, socks and dressing bandages, which might be useful to prevent unpleasant odour or in pathological skin conditions associated with increased bacterial growth such as atopic dermatitis (AD). AD is a frequent skin disorder affecting about 20% of children and about 5% of adults in Western countries. The major pathophysiological causes are impaired skin barrier in parallel with an up regulated immune response towards immediate allergens and a down regulated immune response towards bacterial and viral infections. As a consequence, these patients have higher bacterial loads on their skin. Furthermore, pathologic

bacteria dominate the epidermal colonization. Among them, Staphylococcus aureus species are most frequently found. These bacteria secrete super antigens and toxins that demolish the already impaired skin barrier. This results in the clinical manifestation and exacerbation of atopic dermatitis.
Modern treatment of AD aims at the improvement of skin barrier function and control of bacterial colonization. In particular, the latter is crucial for prevention of exacerbation and improvement of quality of life. For short-term intervention antibiotics can be used, however due to the increasing risks of bacterial resistance, they can only be used occasionally and in short periods. Hence, in this chronic skin disease with continuous need for bacterial control broad-acting antiseptics are preferred.
Recently a new silver containing textile has been developed (Silverwear®). Applying of Silverwear® garments might be useful in inhibiting microbial growth. Ideally, the release of silver (Ag) from the garments should be limited to the uppermost layers of the skin and systemic absorption of Ag should be minimized to avoid toxicity. Thus, to assess the possible health risk data on percutaneous penetration of silver is needed.

Study objective

The main objectives of this study are to investigate 1) in vivo dermal absorption of Ag ions from the Silverwear ® garments in healthy versus atopic skin, 2) effect of dermal exposure to Silverwear ® garments on release of inflammatory cytokines in the skin and 3) antimicrobial effect of Silverwear ® garments.

Study design

The study design is a double-blinded, placebo-controlled in vivo study. The subjects (15 healthy volunteers and 15 AD patients) will wear on their forearms either Silverwear® or placebo sleeve for 5 days, 8 hours a day. On day 1,3 and 5, the uppermost skin layers will be harvested using tape stripping from the skin sites exposed to Silverwear® garments and placebo . The tape strips will be analyzed for the presence of Ag to assess dermal absorption and for the concentration of several inflammatory mediators (IL-1α, IL-1RA and IL-8) to assess possible inflammatory effects. Furthermore, systemic absorption of Ag will be investigated by measuring the concentration of Ag in urine of subjects which will be taken before the study and after the last day of exposure.
The antimicrobial effect of Silverwear® garments will be investigated by swab samples of the skin before and after wearing Silverwear® garments for 1, 3 and 5 days. The swab samples will be analyzed for density of Staphylococcus Aureus.

Study burden and risks

There is no health risk associated with participation in the study.
Participants in the study will experience only minor discomfort. The results of

the study are important because a) they give insight in the antimicrobial efficacy of the silver garment, which may be a useful alternative for using antibiotics, and b) they give insight in the utility and safety of using these kind of garments for people with an impaired skin barrier (e.g. AD patients).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Age between 18 and 55 years
2) Caucasian race of Western European origin

Exclusion criteria

1) Systemic inflammation disease other than AD
2) Skin disease other than AD or contact eczema
3) Use of antihistaminics or inflammation-suppressing medication (e.g. corticosteroids, NSAIDs) or antibiotics one month prior to, and during the investigation
4) Sunbathing or using a tanning bed during 2 months prior to, and during the investigation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2013
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Silver-containing garment
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43656.018.13