Pilot study on the effect of prophylactic versus therapeutic treatment with coal tar and vaseline lanette ointment on the skin barrier repair mechanisms in absence of a chronic inflammatory component.

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To study if the induction of skin barrier proteins, like FLG, by coal tar leads to an improved skin barrier repair and function in the absence of a chronic inflammatory component.

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

Summary

ID

NL-OMON47447

Source
ToetsingOnline

Brief title
Effect of coal tar ointment in the skin barrier repair mechanisms

Condition

- Epidermal and dermal conditions

Synonym
atopic dermatitis

Research involving
Human

Sponsors and support

Primary sponsor: Dermatologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: barrier, coal tar, dermatology, skin

Outcome measures

Primary outcome

Average difference in transepidermal water loss (TEWL) and *natural moisturizing factors* (NMF) after prophylactic and therapeutic treatment with coal tar ointment or the vehicle (petrolatum) during two to four days after skin barrier disruption by tapestripping of the skin.

Secondary outcome

1. Epidermal thickness and stratum corneum thickness due to coal tar and vehicle treatment

2. Expression of skin barrier genes and proteins due to coal tar and vehicle treatment

3. Non-invasive analysis of stratum corneum hydration due to coal tar and vehicle treatment

4. Non-invasive analysis of stratum corneum cohesion due to coal tar and vehicle treatment

5. Non-invasive analysis of corneocyte morphology due to coal tar and vehicle

treatment

6. Macroscopic analysis van the tapestripped skin after coal tar and vehicle

treatment

7. Non-invasive analysis of cytokines in the stratum corneum after coal tar and

vehicle treatment.

Study description

Background summary

Atopic dermatitis (AD) is characterized by a skin barrier disturbance often caused by loss-of-function mutation in the Filaggrin (FLG) gene. Mutations in the FLG gene lead to a diminished protein expression and are the main risk factor for developing AD. Improvement of the skin barrier is considered an important therapeutic strategy. One of the possibilities for such a treatment is the topical application of coal tar. The use of coal tar for skin diseases was first described by Hippocrates and despite the more than 2000 years of use, its mechanism of action remained unidentified until the recent study of our department. We showed that coal tar activates the aryl hydrocarbon receptor (AHR) in skin and thereby induces the expression of important skin barrier proteins and dampens the inflammatory process. This study was an important first step in unraveling the mechanism of action of this ancient therapy. The paradigm that FLG expression is a measure of skin barrier function and that the lack of FLG is causally related to skin barrier dysfunction is under debate. The question remains whether the induction of FLG by coal tar actually leads to an improved skin barrier function in vivo, or that other mechanisms are causing the therapeutic efficacy of coal tar in AD.

Study objective

To study if the induction of skin barrier proteins, like FLG, by coal tar leads to an improved skin barrier repair and function in the absence of a chronic inflammatory component.

Study design

Vehicle-controlled intervention pilot study

Intervention

Healthy volunteers are asked to apply coal tar ointment or the vehicle (petrolatum) on defined skin areas of the lower back during four days.

Study burden and risks

Healthy volunteers visit our clinic three times in seven days time. During four days they will apply locally the ointments on their skin of the lower back. Visits will take between 45 and 120 minutes. During the visits we take non-invasive skin barrier measurements. This will cause no harm or discomfort to the volunteers. The tapestripping procedure is also non-invasive with minimal discomfort. A total of four skin biopsies will be taken (4mm in diameter) under local anesthesia. Skin biopsies of this size do not require stitches and heal without any complications, leaving only a little scar. We will exclude people who are known to develop hypertrophic scars. The expected risks of study are therefore negligible.

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

- Males and females in the age of 18-35 years;- Fitzpatrick skin type 1-3;- Caucasian race

Exclusion criteria

- Presence of inflammatory skin disease;- Fitzpatrick skin type 4-6;- Hypersensitivity and/or intolerance to topical coal tar

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-03-2018
Enrollment:	20

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	pix lithanthracis 5% in vaseline lanette cream
Generic name:	gezuiverde koolteer 5% in vaseline lanette cream

Ethics review

Approved WMO Date:	05-04-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-05-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2017-002223-25-NL
CCMO	NL60891.091.18