In vivo and non-invasive measurement of cytokine release in a mechanistic model of acute skin barrier disruption

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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-OMON42792

Source
ToetsingOnline

Brief title
Cytokine measurement following skin barrier disruption

Condition

- Epidermal and dermal conditions

Synonym
cytokines, inflammatory molecules

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: barrier function, cytokines, tape stripping, transepidermal water loss

Outcome measures

Primary outcome

The main study eindpoints are the levels of cytokines at baseline and at

different time points following acute disruption of the skin barrier by means

of tape stripping.

Secondary outcome

Not applicable

Study description

Background summary

Cytokines are signalling molecules involved in the process of cutaneous irritation. Tape stripping is a minimally invasive model of acute skin barrier disruption which mimics mechanical cutaneous irritation. Being able to measure, in vivo and non-invasively, cytokines release following tape stripping would bring further insights into the inflammatory mechanisms triggered by skin barrier disruption, as well as insights into the repairing mechanisms of the skin barrier. Knowledge of such insights could be applied, for example, in the development/improvement of products/treatments dedicated to the lessening of skin irritation following skin-material interaction (e.g. during shaving or sport).

Study objective

The main objective is to evaluate the cytokine response to tape stripping in vivo, dynamically and non-invasively by means of patches..
The secondary objectives are (i) to correlate the cytokine response with transepidermal water loss (TEWL), a well-known marker of the status of the skin barrier, measured non-invasively; and (ii) to study the effect (if any) of the repetitive application of the patches on the evaluation of the cytokine response.

Study design

This is a descriptive and exploratory pilot study.

Study burden and risks

Participation in the study does not lead to any short term benefit for the volunteers. They are informed of this before giving informed consent. On the long term, volunteers may benefit of better products/treatments created or optimized starting from the insights into the cutaneous irritation following mechanical stimulation (e.g. shavers) gained within this and future studies.

Volunteers need to visit the research site (dermatology department of Radboudumc) three times. On the first visit, tape stripping is performed on four sites of the volar forearm and evaluation (cytokine and transepidermal water loss measurement) is performed at two time points post tape stripping. The first visit lasts 1 hour and 10 minutes. The second and third visits take place 24 and 72 hours after the first visit. During these visits, each 30-minutes long, the skin on which tape stripping was performed is evaluated (cytokine and transepidermal water loss measurement).

The acute disruption of the skin barrier with tape stripping may result in transient skin discomfort. From our point of view, the short follow-up time, the minimally invasive stimulation (tape stripping) and the non-invasive evaluation of cytokines and transepidermal water loss make participation to the study acceptable.

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

Age between 18 and 65 years;
Must be willing to give a written informed consent;
Must have skin type II or III (Fitzpatrick scale)

Exclusion criteria

Pregnancy or lactation;
Atopic predisposition (i.e. history of allergic rhinitis or allergic conjunctivitis, atopic or contact dermatitis, hay fever, asthma);
Any skin disease, including possible lesions found during screening;
Skin types I, IV, V, VI;
Use of immunosuppressive drugs (NSAIDs, biological, topical or systemic corticosteroids)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2015
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2015
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
CCMO	NL54094.091.15