Cytokines in dermal interstitial fluid after single and repeated skin irritation

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

Summary

ID

NL-OMON30412

Source
ToetsingOnline

Brief title
Cytokines in dermal interstitial fluid

Condition

- Epidermal and dermal conditions

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cytokines, interstitial fluid, skin irritation, sodium lauryl sulphate (SLS)

Outcome measures

Primary outcome

To monitor the skin reaction during and after the above mentioned exposures, we will use transepidermal water loss (TEWL) as an effect parameter for the skin barrier function and erythema for the extent of skin inflammation.

The ISF samples will be analysed for the cytokines IL-1α, IL-1RA, IL-1β, IL-2, IL-6, IL-8, IL-10 and TNF-α using ELISA.

Secondary outcome

n.a.

Study description

Background summary

Chronic irritant contact dermatitis (ICD) occurs frequently in several occupations, e.g. hairdressing, nursing and metalworking. The mechanism of the development of chronic ICD and the factors that predispose individuals to this skin disease are not completely understood. Screening of individuals at risk is an important activity in occupational medicine, and such screening must be based on a knowledge of certain predictive characteristics. Understanding the role of cytokines in skin irritation might help in the identification of individual susceptibility factors for chronic ICD.

Study objective

Our objective is to study the changes in cytokine levels in dermal interstitial fluid (ISF) obtained by a minimally invasive technique after single and repeated sodium lauryl sulphate (SLS) exposure compared to untreated skin. The study will give insight in cytokines involved in single and repeated skin irritation. Understanding the mechanism of repeated irritation is of great importance for the identification of factors associated with individual susceptibility to chronic ICD.

Study design

Volunteers will be exposed to SLS at several sites on the volar forearms. On one arm two single SLS exposures (4 hours) will be performed and on the other forearm three sites will be repeatedly exposed to SLS over a 3-week period (6 hours a day, 4 days a week). Different SLS concentrations will be used on each skin site.

The ISF samples are obtained after creating micropores in the stratum corneum using a laser and subsequently ISF is collected using a vacuum pump. Cytokine levels will be determined in the ISF samples obtained after single, repeated and untreated skin.

The investigation will start with a pilot experiment, in which the ISF sampling technique is tested. For this purpose the number micropores to be created in the stratum corneum is determined and the duration of ISF sampling which is needed to obtain sufficient amounts of ISF for the cytokine measurements.

Study burden and risks

n.a.

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 55 years
- Caucasian

Exclusion criteria

- skin diseases
- sunbathing or using a tanning bed 2 months prior to, and during, the investigation
- use of inflammation suppressing medicines (e.g. corticosteroids, NSAIDs) or antibiotics one week prior to, and during the investigation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-03-2006
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO
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	NL11148.018.06