In vivo and non-invasive measurement of cytokine release in a model of acute and local skin inflammation

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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-OMON43271

Source
ToetsingOnline

Brief title
Cytokine measurement following acute and local skin inflammation

Condition

- Epidermal and dermal conditions

Synonym
cytokines, inflammatory molecules

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cytokines, histamine, iontophoresis

Outcome measures

Primary outcome

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

different time points following local skin inflammation elicited by histamine

iontophoresis.

Secondary outcome

Not applicable.

Study description

Background summary

Cytokines are signalling molecules involved in the process of inflammation and cutaneous irritation. A previous pilot study performed by our research group showed that cytokines could be measured, in vivo and non-invasively, after acute disruption of the skin barrier by means of repetitive application of an adhesive tape (*tape stripping*). It would be interesting to evaluate whether the profile of cytokine release is different if inflammation is elicited with minimal skin barrier impairment by means of histamine iontophoresis. These insights could be of interest in the field of transdermal drug delivery, in which iontophoresis is frequently used to enhance the penetration of actives through the skin.

Study objective

The main objective is to evaluate the cytokine response to histamine iontophoresis in vivo, dynamically and non-invasively by means of transdermal analysis patches. The secondary objective is to correlate the cytokine response with morphological features of the skin obtained with reflectance confocal microscopy (RCM).

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 inflammation and cutaneous irritation following iontophoresis (e.g. new transdermal drug delivery systems) gained within this and future studies. Volunteers need to visit the research site (dermatology department of Radboud University Medical Center) two times. On the first visit, histamine iontophoresis is performed on the volar forearm and non-invasive evaluation is performed at two time points post stimulation. The first visit lasts 1 hour and 40 minutes. The second visit takes place 24 hours or 72 hours after the first visit. During this 30 minutes-long visit the skin on which histamine iontophoresis was performed is non-invasively evaluated. The local skin inflammation elicited by histamine iontophoresis may result in transient skin discomfort (itch, swelling and redness). From our point of view, the short follow-up time, the minimally invasive stimulation (histamine iontophoresis) and the non-invasive evaluation of the skin response (cytokines and RCM) 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 I, II or III (Fitzpatrick scale).

Exclusion criteria

Diagnosis of histamine hypersensitivity;
Predisposition to respond allergic (including diagnosis of allergy to silver or to other device-related material);
Presence of cardiac pacemakers or other implanted electric devices;
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 type IV, V, VI (Fitzpatrick scale);
Use of immunosuppressive drugs (NSAIDs; biologicals; topical or systemic corticosteroids);
Use of antihistamines drugs;
Use of medication for hypertension with airway constricting activity (e.g. beta blockers);
Excessive sun exposure or tanning at the moment of screening.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	14-04-2016
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	NL56943.091.16