A study of skin responses to histamine

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

Summary

ID

NL-OMON41203

Source
ToetsingOnline

Brief title
Skin responses to histamine

Condition

- Epidermal and dermal conditions

Synonym
"delicate skin", "hyper-reactive skin"

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Industry: Royal Philips N.V;acting through Philips Research

Intervention

Keyword: iontophoresis, sensitive skin, skin irritation, skin measurement

Outcome measures

Primary outcome

The main study endpoint consists in gaining insights into the differences in

the average responses to histamine, both topically and iontophoretically

applied, in sensitive and non-sensitive skin.

Secondary outcome

Not applicable.

Study description

Background summary

Sensitive skin has been defined as a subjective cutaneous hyper-reactivity to stimuli, with or without objective signs of skin irritation. Subjective sensations commonly present are itching, burning, stinging and tightness. Despite the prevalence proves to be high across industrialized countries, no consensus on the mechanisms involved has yet emerged. Gaining insights in the mechanism(s) of sensitive skin has relevant importance from both a medical and cosmetic perspective.

This study belongs to a wider project whose aim is to obtain an understanding of sensitive skin in terms of key mechanism(s) involved. This task is carried out through the use of different provocations to elicit skin reactions. Provocations target mechanisms suggested to be involved in sensitive skin and skin reactions are evaluated with different tools. This study focuses on histamine iontophoretically and topically applied as provocations to be included in the project.

Study objective

The primary objective of this study is to detect significant difference in the average response to histamine, topically and iontophoretically applied to the skin, between sensitive and non-sensitive skin volunteers. Skin reactions are assessed with non-invasive methods like Visual Analogue Scale (VAS) scores, skin photographs, clinical assessments and non-invasive biophysical skin measurements, and with skin biopsies. Volunteers are included in the sensitive or non-sensitive skin group according to a questionnaire.

Study design

This is a descriptive explorative pilot study.

Study burden and risks

Participation in the study does not lead to 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 and treatments created or optimized starting from the insights into the mechanism(s) of sensitive skin gained within this project.

Volunteers are asked to fill in a questionnaire about their skin sensitivity and to visit the clinical site two or three times. The first visit (1.5 hours) includes stimulation with histamine, which will be applied iontophoretically and topically on the lower back and topically on the volar forearm. Evaluation is performed at several time points and consists in measuring biophysical parameters non-invasively, clinically assessing edema and erythema, taking skin photographs, assessing the VAS score and taking one skin biopsy from a non-stimulated skin spot on the lower back. Two other skin biopsies will be taken at four different time points (1h, 8h, 24h and 72h) from the skin spot stimulated with iontophoresis, according to a randomization process. Therefore, the volunteers will need to visit the clinical site one or two other times and each of these visits will take approximately 40 minutes. The stimulation with histamine and the biopsies may result in skin discomfort. The risk of visible scar formation is low, since the lesion is small. Considering this, we are of the opinion that a study with short follow-up time and only minimally invasive techniques is legitimate.

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
Willing to give a written informed consent
Skin type II or III (Fitzpatrick scale)

Exclusion criteria

Diagnosis of histamine hypersensitivity
Diagnosis of silver allergy
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
Any bleeding disorder
Use of immunosuppressive drugs (NSAIDs; biologicals; topical or systemic corticosteroids)
Use of antihistamines drugs
Increased risk to develop hypertrophic scars

Study design

Design

Study type:	Observational invasive

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2015
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-07-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-11-2016
Application type:	Amendment
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	NL49756.091.14