Sensitive skin and skin irritation. Characteristics and diagnostic tools.

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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-OMON38547

Source
ToetsingOnline

Brief title
Sensitive skin characteristics

Condition

- Epidermal and dermal conditions

Synonym
Sensitive skin, skin irritation

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: biophysical measurements, photothermolysis, Sensitive skin, skin irritation

Outcome measures

Primary outcome

Main study parameters/endpoints: This pilot study is an explorative observational study with the objective to detect difference between sensitive skin and non-sensitive skin. Baseline parameters and skin response following different stimuli are investigated. The main parameters are abnormal differentiation parameters and biophysical parameters as a* value, stratum corneum hydration and transepidermal water loss.

Secondary outcome

n.a.

Study description

Background summary

Although the prevalence of sensitive skin proves to be extensive across industrialized countries, the phenomenon is imprecisely defined and morphologic or physiological identification has failed. Sensitive skin is mainly characterized by exaggerated perceptions burning, stinging and itching sensations and pain. Translation of the subjective perceptions to more objective biophysical measurements might be the key in the identification and understanding of sensitive skin. According to our knowledge, it is not clear whether the consumers perception of excessive discomfort following light-based or mechanical challenges is related to a *more general* sensitive skin.

Study objective

Objective: The primary objective is to investigate whether sensitive skin fundamentally differs from *normal skin*. In this study, we try to identify the morphological and functional characteristics of sensitive skin by provocation of the skin with different challenges and evaluation by noninvasive biophysical

measurements, and immunohistochemical analysis of biopsies. By evaluation of sensitive skin from different perspectives, we try to identify a diagnostic tool to detect sensitive skin. Furthermore, by mechanical provocation and provocation with light, the skin reactions are compared to assess whether these reactions have similarities and may refer to a sensitive skin as a container term with similar skin reactions triggered by different challenges.

Study design

Study design: The pilot study is an explorative observational study. Subjects with sensitive skin are compared with subjects without sensitive skin.

Study burden and risks

Participation in the study does lead to direct benefit for the subjects. Before the volunteers will give informed consent, we will inform them that attending in this research is not in any way beneficial for them. When the volunteer, despite of this, does wish to attend in this study, most likely he or she will do this to make a contribution to science. Considering this, we are of the opinion that a study with short follow-up time and only minimal invasive techniques, is legitimate. Subjects are selected by questionnaire. In total, the volunteers visit the research site three times. The first visit includes stimulation in the morning and evaluation after 30 minutes and after 8 hours and therefore, this first visit is time consuming. Subjects are stimulated with one of the three selected methods, which all may result in physical discomfort, experienced as prickling or burning feeling or itch. Slight erythema is expected to occur. The skin responses are assessed by non-invasive methods that do not significantly interact with the skin. Punch biopsies may cause some physical discomfort. Local anaesthesia is performed before punch biopsies are performed and this procedure may be experienced as painful. The risk of visible scar formation is low, since the lesion is small.

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

Specification: research protocol (section 3)
To enter this pilot study, volunteers must meet the following criteria:
- Age between 18 and 65 years of age
- Volunteers must be willing to give a written informed consent
- Volunteers must have skin type II or III (Fitzpatrick scale)
- Non-sensitive skin or sensitive skin (both determined by a questionnaire)

Exclusion criteria

•Any skin disease at the moment of screening.
•Volunteers with a predisposition to respond allergic. History of atopic dermatitis, asthma, allergic rhinitis or allergic conjunctivitis.
•Volunteers with a allergic contact dermatitis in history.
•Volunteers with skin type I, IV, V or VI (Fitzpatrick scale)
•Use of immunosuppressive drugs (NSAIDs; biologicals; topical or systemic corticosteroids)
• Recent excessive sun exposure or tanning (<2 weeks).
volunteers with predisposition to develop hypertrophic scars.
Volunteers with bleeding disorders.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2014
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2013
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	NL43331.091.13