Effects of visible light on inflammation and skin barrier recovery following acute perturbation

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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-OMON43517

Source
ToetsingOnline

Brief title
Effect of visible light on skin barrier recovery

Condition

- Epidermal and dermal conditions

Synonym
skin barrier, stratum corneum

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Electronics Nederland B.V.;acting through Philips Research

Intervention

Keyword: iontophoresis, light, non-invasive measurement, skin barrier

Outcome measures

Primary outcome

The main study parameters are the recovery of the skin barrier after tape stripping, measured with transepidermal water loss (marker of skin barrier status), and the clearance of inflammation after histamine iontophoresis, measured with a* value (marker of skin redness). Both measurements are non-invasive. Tape stripping and histamine iontophoresis will be performed twice on the same volunteer, on two consecutive weeks. On one occasion stimulation is followed by irradiation, in the other no irradiation is performed serving as control.

Secondary outcome

Not applicable

Study description

Background summary

Recent studies have demonstrated the presence of photoreceptors in the skin and suggest that visible (blue and red) light has biological effects in the skin, including decrease of inflammation, decrease of epidermal proliferation and enhancement of skin barrier repair. In this study we address the potential of red and blue light in fastening the recovery of skin homeostasis after experimentally-induced skin barrier disruption and inflammation. Light-based treatments/products could be developed starting from the outcomes of this study to diminish adverse skin reactions of people with sensitive skin.

Study objective

The primary objective of this study is to evaluate whether the recovery of the

skin barrier after acute perturbation by repetitive application of adhesive tape (*tape stripping*) is accelerated following irradiation with visible light. The secondary objective of this study is to evaluate whether the clearance of inflammation following application of histamine via iontophoresis is accelerated following irradiation with visible light. Four different irradiation settings will be employed and the primary and secondary objectives will be evaluated within each irradiation setting.

Study design

This is an observational case-control pilot study, where volunteers serve as their own internal control, performed at the dermatology department of Radboud University Medical Center

Study burden and risks

This study does not lead to any short term benefit for the volunteers, as clearly expressed in the information provided. On the long term, volunteers may benefit of better products/treatments created starting from the insights into the effects of visible light on skin homeostasis gained within this study. The study is performed on six visits spanned over two consecutive weeks. The study procedures are the same for each week: on the first visit, stimulation with tape stripping and histamine iontophoresis is performed on the volar forearm and skin reactions are evaluated up to 1 hour after stimulation. These are also evaluated later in the week, at 24 hours and 72 hours. The only difference is that, in one of the two weeks, stimulation is followed by irradiation with visible light. Total study duration for each volunteer is five hours. Stimulation may result in transient skin discomfort, itch and redness and last up to a few hours (histamine) and days (tape stripping). From our point of view, the short follow-up time, the minimally invasive stimulations and the non-invasive readouts 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

1. skin type I, II or III (Fitzpatrick scale);
2. 18 - 40 years old;
3. willing to give written informed consent

Exclusion criteria

1. diagnosis of histamine hypersensitivity;
2. presence of cardiac pacemakers or other implanted electric devices;
3. pregnancy or lactation;
4. atopic predisposition (i.e. allergy, atopic/contact dermatitis, hay fever, asthma);
5. any current (skin) disease including conditions causing photosensitivity;
6. predisposition to respond allergic;
7. use of immunosuppressive drugs;
8. use of antihistamines drugs;
9. use of medication for hypertension with airway constricting activity;
10. use of medication with photosensitizing effects;
11. skin type IV, V, VI (Fitzpatrick scale);
12. excessive sun exposure or tanning less than 2 weeks before the beginning of the study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2016
Enrollment:	44
Type:	Actual

Medical products/devices used

Generic name:	HealthyLight LED Lamp V2
Registration:	No

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-09-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-05-2017
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

ID: 20423
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56421.091.16
OMON	NL-OMON20423