Gepubliceerd: 20-07-2016 Laatst bijgewerkt: 13-12-2022

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

Health condition

Skin barrier recovery

Ondersteuning

Primaire sponsor :	Philips Research
Overige ondersteuning :	Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Measurement of Transepidermal Water Loss (TEWL) at baseline and at 1 hour, 24 hours and 72 hours after tape stripping.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.
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 population: 44 healthy human volunteers are included (divided in four groups of 11 people each, one
group per irradiation setting), based on power analysis. Subjects must have skin type I, II or III (Fitzpatrick scale)
and be 18 - 40 years old. Exclusion criteria include: 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.
Main study parameters/endpoints: 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.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Onderzoeksopzet

Day 1, Day 2, Day 4, Day 8, Day 9, Day 11

Onderzoeksproduct en/of interventie

Volunteers served as their own internal control.
Stimulation with tape stripping and histamine iontophoresis performed on the volar forearm, +/- followed by irradiation with visible light - then skin reactions are evaluated at different time points

Contactpersonen

Publiek

Philips Research Eindhoven
Celine Reverseau
High Tech Campus 34
Eindhoven 5656 AE
The Netherlands
m:+31-6-31639778

Wetenschappelijk

Philips Research Eindhoven
Celine Reverseau
High Tech Campus 34
Eindhoven 5656 AE
The Netherlands
m:+31-6-31639778

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age between 18 and 40 years;
- Subject must be willing to give a written informed consent;
- Subject must have skin type I, II or III (Fitzpatrick scale)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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 and conditions causing photosensitivity (e.g. porphyria, polymorphic light eruption, chronic actinic dermatitis, actinic prurigo and solar urticaria)
- 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);
- Use of medication with photosensitizing effects;
- Excessive sun exposure or tanning at the moment of screening.
In order to be compliant with the guidelines for the non-invasive biophysical skin measurements volunteers are also asked to:
- Avoid the application of creams, body lotions, other topicals on the skin sites to be assessed (volar forearms) on the days of the experiments and up to 24 hours before each visit.
- Avoid excessive sun exposure on the skin sites to be assessed on the days of the experiments.

Onderzoeksopzet

Opzet

Type :	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel :	Parallel
Toewijzing :	Geen controle groep
Controle :	N.v.t. / onbekend

Deelname

Nederland

Status :	Werving gestopt
(Verwachte) startdatum :	15-08-2016
Aantal proefpersonen :	44
Type :	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort :	Niet van toepassing

Registraties

In dit register bekende (historische) registraties

Geen registraties gevonden

In overige registers

Source : NTR

Register	ID
NTR-new	NL5820
NTR-old	NTR5975
CCMO	NL56421.091.16

Resultaten