Skin habituation after repeated suberythemal UV-exposure

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To explore skin adaptation after repeated sub-erythemal UV-dose and individual factors that might underlie this process.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON51636

Source
ToetsingOnline

Brief title
Skin habituation

Condition

- Epidermal and dermal conditions

Synonym
non-melanoma skin cancer, Skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Winst reserve

Intervention

Keyword: In vivo, Skin habituation, UV-exposure

Outcome measures

Primary outcome

Minimal erythemal dose-levels (MED)

Secondary outcome

changes in thickness of stratum corneum (SC) and epidermal thickness, SC levels

of immunological markers and urocanic acid isomers, levels of 25(OH)D3 in serum

Study description

Background summary

Skin adaptation after UV-exposure is an important field of research. In general, skin adaptation and underlying mechanisms are largely unknown, while this knowledge is of interest for development of prevention strategies in the workplace, the general population and for skin therapy. For several immune mediated skin diseases, suberythemal UV-therapy by means of a home-installed UV-device has proven to be a safe, effective and patient-friendly approach. (21) The role of individual characteristics such as skin phototype and SC thickness on the changes in the skin barrier, inflammatory- and immune response induced by repeated suberythemal UV exposure is scarce.

Study objective

To explore skin adaptation after repeated sub-erythemal UV-dose and individual factors that might underlie this process.

Study design

Experimental exposure study in healthy volunteers (a single-center)

Intervention

Broad-spectrum UV-irradiation with repeated use of a home-installed UV-device (the Sunshower medical) of the back skin at suberythemal dose, three times every week during 10 minutes (0,8 SED per time)

Study burden and risks

UV-source which resembles sunlight will be installed at homes of volunteers. Subjects will visit the research site (AMC, Department of Dermatology) six times: intake visit, after 1,5 and 3 months. The day after every consultation, the participants will be evaluated on erythema after application of the MED device. At each visit, samples of the stratum corneum will be collected, and stratum corneum thickness will be measured with non-invasive Optical Coherence Tomography. At the first and last consultation, blood samples will be collected. Minimal erythemal dose (MED) will be measured after every consultation. The day after every consultation, participants are asked to come back to the research unit to determine erythema.There is no direct benefit for the patient.

Collection of the stratum corneum will be performed by using adhesive tapes (12 consecutive tapes from one skin site), which is a minimally invasive procedure, and has often been applied in own studies and elsewhere. The epidermal thickness is measured with Optical Coherence Tomography (OCT). This is a non-invasive optical imaging technique that uses low-power infrared laser light. MED will be measured with a MED measurement device. Blood serum is collected to measure 25(OH)D3 levels. Each visit will take approximately 45 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Individuals between 18 and 35 years.
- Fitzpatrick skin types II, III, IV or VI
- Individuals free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
- Individuals who have read, understood, and signed an informed consent document relating to the specific study to which they are subscribing.

Exclusion criteria

- Individuals taking medication which in the opinion of the investigator would mask or interfere with the results.
- Individuals with chronic skin allergie
- Individuals with suntan or sunburn.
- Individuals with abnormal reactions to the sun.
- Individuals who use oral supplementation of vitamin D
- Subjects who used sun beds or were extensively exposed to UVR in the previous 30 days (e.g. during holidays), or are planning on doing so during the study
- Subjects who consumed alcohol 1 day prior to MED assessment

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	06-02-2023
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Sunshower Combi
Registration:	No

Ethics review

Approved WMO Date:	12-01-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL82865.018.22