Assessment of the protective effect of sunscreen by measuring UV-biomarkers

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Determine the protective effects of sunscreens against UV-radiation by measuring biomarkers in the stratum corneum.

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

Summary

ID

NL-OMON48352

Source
ToetsingOnline

Brief title
Protective effect of sunscreen

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: DGUV (Deutsche Gesetzliche Unfall Versicherung)

Intervention

Keyword: biomarkers, in vivo, Sunscreen, UV-radiation

Outcome measures

Primary outcome

The levels of urocanic acid isomers, immunological factors (chemokines,

cytokines, MMP (metalloproteinases)), and angiogenesis factors in the the

stratum corneum.

Secondary outcome

n.a.

Study description

Background summary

Non-melanoma skin cancer (NMSC; synonym: keratinocyte skin cancers) is a growing health problem in occupations associated with high doses of solar ultraviolet radiation (UVR). In several EU countries NMSC are recognized as an occupational disease. Various prevention strategies including application of sunscreens, administrative policies or education have recently been developed. Efficacy of these interventions has insufficiently been evaluated, partly due to the lack of relevant outcomes. In our previous work, we determined various biomarkers of DNA damage and immune response to monitor the effects of UVR, in the stratum corneum. In this follow-up study we will use the previously determined biomarkers to measure the protective effect of sunscreens in vivo.

Study objective

Determine the protective effects of sunscreens against UV-radiation by measuring biomarkers in the stratum corneum.

Study design

Intervention study in healthy volunteers (single-center). Exposure to UV-radiation and two sunscreens. Part of the back skin (2 x 30 cm2) protected with sunscreen, will be exposed to an UVR-dose of 150 mJ/cm2. Another part of the back skin (4 x 30 cm2) will be exposed to an UVR-dose of 7.5, 15, 30 and 60

mJ/cm2, unprotected.

Intervention

Broad-band UV exposure of the unprotected back skin of the volunteers at UV-dose of 7.5, 15, 30 and 60 mJ/cm2. The sunscreen protected (SPF 50+) skin will be exposed at a UVR-dose of 150 mJ/cm2. 5 times weekly during 1 week. Samples of the stratum corneum will be collected on day 1, 3, 5 and 6. The collection of the stratum corneum will be carried out using adhesive tapes. This procedure is not invasive and painless.

Study burden and risks

Besides mild redness of the skin after first exposures no other effects are expected. The UVR-doses used in the present study, are similar to those in large numbers of studies researching the sun protection factor (SPF) of sunscreens.
The used sunscreens are commercially available.

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

Male and female individuals between 18 and 65 years.
Fitzpatrick skin types II or III.
Free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator.
Individual who has read, understood and signed an informed consent document relating to the specific study to which he/she is subscribing.
Individuals with no known abnormal response to sunlight (e.g. polymorphic eruption) or (ingredients of) sunscreens.
Willingness to actively participate in the study and come to the scheduled visits
Willingness to discontinue the use of detergents (e.g. soaps) and cosmetics products (e.g. creams, moisturizers) in the treatment area throughout the course of the study
Willingness to avoid any exposure of the test area to artificial or natural ultraviolet light throughout the course of the study

Exclusion criteria

Taking medication which in the opinion of the investigator would mask or interfere with the results.
With chronic skin allergies.
With suntan of sunburn
Breastfeeding
Pregnancy or intention to become pregnant over the duration of the study
Participation in, or being in the waiting period for another study
Individual with moles, tattoos, scars, irritated skin, hairs, etc. at the test area that could influence the investigation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2019
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Sunscreen
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-09-2019
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	NL70109.018.19