Non-invasive biomarkers of UV-radiation

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Primary Objective: to explore whether UVB exposure leads to detectable changes of the biomarkers of the skin barrier, immune response and DNA-damage in urine and stratum corneum Secondary Objective(s): to explore the profile of biomarkers in...

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

Summary

ID

NL-OMON47995

Source
ToetsingOnline

Brief title
UV-radiation biomarkers

Condition

- Epidermal and dermal conditions

Synonym
skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biomarkers, in vivo, UV-radiation

Outcome measures

Primary outcome

The levels of urocanic acid isomers, MMP, cytokines and DNA-photoproducts measured in the stratum corneum and/or urine at different time points during a 3-weeks study

Secondary outcome

The levels of urocanic acid isomers, MMP, cytokines and DNA-photoproducts at different stratum corneum depths (i.e. 1st to 12th collected tape from the same skin site)

Study description

Background summary

Non-melanoma skin cancers (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. Various biomarkers of DNA damage and immune response have been proposed to monitor the effects of UVR, however so far they have been determined in blood or skin biopsy. Development of non-invasive biomarkers e.g. in urine or in the stratum corneum would therefore be of great value.

Study objective

Primary Objective: to explore whether UVB exposure leads to detectable changes of the biomarkers of the skin barrier, immune response and DNA-damage in urine and stratum corneum

Secondary Objective(s): to explore the profile of biomarkers in relation to the

depth of the stratum corneum

Study design

Explorative study in healthy volunteers (a single-center)

Intervention

Broad-band UV exposure of the back skin of the volunteers at sub-erythemal dose of 20-30 mJ/cm2, 3 times weekly during 3 weeks. Before each UV-irradiation samples urine and stratum corneum will be collected. The collection of the stratum corneum will be carried out by using adhesive tapes. This procedure is not invasive and painless.

Study burden and risks

Besides slight redness of the skin after first exposures no other effects are expected

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 individuals between 18 and 65 years.
* Fitzpatrick skin types II or III.
* 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 relat-ing to the specific study to which they are subscribing.
* Individuals with no known abnormal response to sunlight (e.g. polymorphic eruption).

Exclusion criteria

* Individuals taking medication which in the opinion of the investigator would mask or in-terfere with the results.
* Individuals with chronic skin allergies.
* Individuals with abnormal reaction to the sun.
* Subjects who used sun beds in the previous 30 days.

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):	25-03-2019
Enrollment:	12

Type:	Actual

Medical products/devices used

Generic name:	UV-radiation
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-03-2019
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	NL68855.018.19