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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25722

Source
NTR

Brief title
UVSUN

Health condition

None

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: University of Osnabrueck

Intervention

Outcome measures

Primary outcome

Urocanic acid isomers, immunological mediators, and angiogenesis factors in the stratum corneum at baseline and after UVR.

Secondary outcome

None

Study description

Background summary

Rationale: Non-melanoma skin cancer (NMSC; synonym: keratinocyte skin cancer) 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 have recently been developed. Efficacy of these interventions has insufficiently been evaluated, partly due to the lack of relevant outcomes. In this study we will investigate whether we can identify biomarkers which are suitable to assess the protective effect of sunscreens in vivo. Currently, the effectiveness of sunscreens is expressed as sun protecting factor (SPF), which is a measure for how long sun exposure can be prolonged before perceptible erythema is induced. SPF is estimated from the minimal erythema dose (MED), a rather subjective and insensitive end-point which does not necessarily reflect biological changes relevant for development of NMSC.
Objective: 1) to assess the protective effect of two different sunscreens (SPF 50+) by measuring the SC biomarkers, and 2) to establish dose-relationship between various biomarkers and UVR.
Study design: Intervention study in healthy volunteers (a single-center study).
Study population: 12 healthy, male or female, volunteers, 18-65 years old, with Fitzpatrick phototype II or III.

Study objective

Identify biomarkers in the stratum corneum which are suitable to assess the protective effect of sunscreens in vivo.

Study design

4

Intervention

Repeated UVR exposure of the back skin during 5 days (Monday to Friday). The UVR dose on the sunscreen protected skin will be 150 mJ/cm2 (approximately 5 MED). Two different sunscreens with a declared SPF 50+ will be investigated, both are commercially available, one of them as an over-the-counter (OTC) product and another as a medical device (CE class I). The dose-response relationship will be assessed on the unprotected skin for the UVR doses of 7.5, 15, 30, and 60 mJ/cm2 (approximately 0.25, 0.5, 1, and 2 MED, respectively). The SC samples will be collected on Monday, Wednesday, Friday, and on the following Monday.

Contacts

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Eligibility criteria

Inclusion criteria

- Between 18 and 65 years of age
- Fitzpatrick skin type 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
- 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
- Individual with no known abnormal response to sunlight (e.g. polymorphic eruption) or to sunscreen (ingredients of sunscreen)

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 the 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	03-10-2019
Enrollment:	12
Type:	Unknown

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-10-2019
Application type:	First submission

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
NTR-new	NL8094
Other	METC AMC : 158 / NL70109

Study results