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

Gepubliceerd: 17-10-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25722

Bron
NTR

Verkorte titel
UVSUN

Aandoening

None

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: University of Osnabrueck

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	03-10-2019
Aantal proefpersonen:	12
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-10-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8094
Ander register	METC AMC : 158 / NL70109

Resultaten