Ultraviolet related DNA-damage in skin of patients with atopic dermatitis and atopic status in relation to the use of Myfortic®.

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The use of the oral immunosuppressant Myfortic® in the treatment of atopic dermatitis might be responsible for the delay the repair of DNA-damage in the skin after UV-exposition.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28786

Bron
NTR

Verkorte titel
Effect of Myfortic® on UV-induced DNA-damage and atopic status

Aandoening

N/A

Ondersteuning

Primaire sponsor: UMC Utrecht, department of Dermatology:
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Overige ondersteuning: Novartis Pharma B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference between the percentage in repair of cyclobutane pyrimidine dimers (CPD's) before and after treatment with Myfortic is the primary study outcome.

Toelichting onderzoek

Achtergrond van het onderzoek

Atopic dermatitis (AD) is a chronic inflammatory disease, presenting with exacerbations and remissions, leading to an impaired quality of life in a large group of patients. Continuously there is being searched for new and improved treatments. Myfortic (mycophenolic acid) is a promising immunosuppressive drug for the treatment of severe AD patients, especially those patients with an atopic disposition.

- In literature a possible relationship between the use of oral immunosuppressive drugs and the development of non-melanoma skin cancer is suggested. There have been no in-vivo studies performed that evaluate the effect of oral immunosuppressive drugs on UV-related DNA-damage.

- No in-vitro or in-vivo data exist on the effect of Myfortic on DNA-repair after UV irradiation. The primary aim is to study the effect of treatment of severe AD patients with Myfortic on DNA-repair after irradiation with UVB.

Secondary aims are to study the effect of Myfortic® on clinical efficacy and safety in severe AD patients, with special attention to the effect of treatment on atopic status, measured as total IgE and specific IgE, skin prick tests and atopy patch tests.

Doel van het onderzoek

The use of the oral immunosuppressant Myfortic® in the treatment of atopic dermatitis might be responsible for the delay the repair of DNA-damage in the skin after UV-exposition.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

10 patients in total with atopic dermatitis are to be included in the study. The inclusion takes place after the physician has indicated that treatment with oral immunosuppressive drugs is

necessary. The informed consent intake will be performed by the researcher. At inclusion a screening will be done to evaluate the severity of the eczema and the atopic state (total and specific IgE, skinpricktest and atopy patch test) of the patient.
Subsequently we will compare UV-irradiated, non-laesional skin prior to treatment (control) to UV-irradiated, non-laesional skin treated with Myfortic during 12 weeks (intervention). The Minimal Erythema Dose (MED) will be determined prior to actual irradiation. Punch biopsies will be taken immediately after irradiation with 2 MED and after 24 hours. A reference biopsy will be taken from skin that is not irrradiated. The whole proces will be repeated after 12 weeks of treatment.
To evaluate the atopic status after 12 weeks of treatment, we will repeat the skinpricktest and atopy patch test. The final clinical evaluation of therapy will be performed after 16 weeks.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age from 18 years;

2. Atopic dermatitis according to the criteria of Hanifin and Rajka;

3. Insufficient respons to topical therapy alone;

4. The physician estimates that treatment with oral immunosuppressiva agents is indicated.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with any known hypersensitivity to mycofenolic acid or other components of the formulation;

2. Oral immunosuppressive treatment in the last 6 weeks;

3. Concomittant UV therapy or UV therapy in the last two months;

4. Contact with UV on the laesional skin for the last two months;

5. Patients with thrombocytopenia (<75.000/mm3), with an absolute neutrophil count <1.500/mm3 and/or leukocytopenia (<2.500/mm3) and/or hemoglobin <6,0g/dl priot to enrollment;

6. Patients who have received an investigational drug within two weeks prior to screening;

7. Patients with a history of malignancy within the last five years;

8. Females of childbearing potential who are planning to become pregnant, who are pregnant and/or lactating, who are unwilling to use effective means of contraception;

9. Patients with an immunologic disorder (like RA, SLE or M. Sjögren) or a preexistent dermatologic disorder that worsens in combination with UV (like LE or photosensitive eczema);

10. Presence of clinically significant infection requiring continued therapy, severe diarrhea or uncontrolled diabetes mellitus that would interfere with the appropiate conduct of the study.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL749
NTR-old	NTR760
Ander register	: 14196
ISRCTN	ISRCTN23778671

Resultaten

Samenvatting resultaten
N/A