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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28786

Source
NTR

Brief title
Effect of Myfortic® on UV-induced DNA-damage and atopic status

Health condition

N/A

Sponsors and support

Primary sponsor: UMC Utrecht, department of Dermatology:
Dr. M.S. de Bruin-Weller
Dr. E.F. Knol
Prof. dr. C.A.F.M. Bruijnzeel-Koomen
Source(s) of monetary or material Support: Novartis Pharma B.V.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary study outcomes are the atopic state before and after treatment with Myfortic®.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	10
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL749
NTR-old	NTR760
Other	: 14196
ISRCTN	ISRCTN23778671

Study results

Summary results
N/A