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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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30341

Source
ToetsingOnline

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

Condition

- Skin neoplasms malignant and unspecified
- Epidermal and dermal conditions

Synonym
atopic dermatitis, atopic eczema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Novartis

Intervention

Keyword: atopic dermatitis, atopic status, DNA-damage, Myfortic®

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

The secundary study outcome is the atopic state before, during 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 (mycofenolic 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.

Study objective

The primary aim is to study the effect of treatment of severe AD patients with Myfortic on DNA-repair after irradiation with UVB.
A secondary aim is to study the effect of treatment of severe AD patients on atopic status, measured as total IgE and specific IgE, skin prick test and atopy patch test.

Study design

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 to UV-irradiated, non-laesional skin treated with Myfortic during 12 weeks. 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 biopsie 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.

Intervention

As mentioned in study design.

Study burden and risks

UV-irradiation can cause some skin irritation. If necessary the skin can be treated with a mild corticosteroid ointment. There is a possibility that the biopted skin shows some hypopigmentation in comparison to the surrounding skin.
During the trial 6 times a blood control will be performed with a maximum of 5 ml blood extra each time to evaluate the atopic status in the blood. Normally there is also blood control each control visit (+/- 10 ml each time) to exlude side effect of the treatment with mycofenolic acid. Furthermore twice a skinpricktest and a atopy patch test will be performed to evaluate the atopic status during Myforic treatment. We assess the severity of the eczema at each visit by means of a clinical skin assessment score (SCORAD). Besides above-mentioned there is no burden for the patient. The risks associated with participation are minimal. The total time investment adds up to approximately 280 minutes (4,5 hours) divided over 12 visitis.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX, Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX, Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age from 18 years
- atopic dermatitis according to the criteria of Hanifin and Rajka
- insufficient respons to topical therapy alone
- the physician estimates that treatment with oral immunosuppressiva agents is indicated.

Exclusion criteria

- patients with any known hypersensitivity to mycofenolic acid or other components of the formulation.
- oral immunosuppressive treatment in the last 6 weeks.
- concomittant UV therapy or UV therapy in the last two months.

- contact with UV on the laesional skin for the last two months.
- 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.
- patients who have received an investigational drug within two weeks prior to screening
- patients with a history of malignancy within the last five years.
- 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.
- 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).
- 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 phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2007
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Myfortic®
Generic name:	mycophenolic acid

Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2006-004668-30-NL
CCMO	NL14196.041.06
Other	NL14196.041.06