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Ultraviolet related deoxyribonucleic acid damage in skin of patients with atopic dermatitis and atopic status in relation to the use of Myfortic®

Submission date
22/11/2006

Recruitment status
No longer recruiting

Registration date
22/11/2006

Overall study status
Completed

Last Edited
05/12/2006

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.dermatologyutrecht.nl/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14196

Study information

Scientific Title

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

Study objectives
Our hypothesis is that in patients with atopic dermatitis which use topical tacrolimus 0.1% the repair of DeoxyriboNucleic Acid (DNA)-damage in the skin is delayed. The repair of DNA-damage in the skin of patients with atopic dermatitis which use a class II corticosteroid is not delayed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Clinical Trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
Ten 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 Immunoglobulin E [IgE], skin-prick test and atopy patch test) of the patient.

Subsequently we will compare UV-irradiated, non-lesional skin prior to treatment (control) to UV-irradiated, non-lesional 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 two MED and after 24 hours. A reference biopsy will be taken from skin that is not irrradiated. The whole process will be repeated after 12 weeks of treatment.

To evaluate the atopic status after 12 weeks of treatment, we will repeat the skin-prick test and atopy patch test. The final clinical evaluation of therapy will be performed after 16 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Myfortic®

Primary outcome measure
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 measures
1. The atopic state before and after treatment with Myfortic®.
2. The evaluation of the efficacy of initial high dosing with Myfortic® in order to induce rapid improvement of the disease.

Overall study start date
01/10/2006

Completion date
01/05/2007

Eligibility

Key inclusion criteria
1. Age from 18 years
2. Atopic dermatitis according to the criteria of Hanifin and Rajka
3. Insufficient response to topical therapy alone
4. The physician estimates that treatment with oral immunosuppressive agents is indicated

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
10

Key exclusion criteria
1. Patients with any known hypersensitivity to mycofenolic acid or other components of the formulation
2. Oral immunosuppressive treatment in the last six weeks
3. Concomitant Ultraviolet (UV) therapy or UV therapy in the last two months
4. Contact with UV on the lesional skin for the last two months
5. Patients with thrombocytopenia (less than 75,000/mm^3), with an absolute neutrophil count less than 1,500/mm^3 and/or leukocytopenia (less than 2,500/mm^3) and/or haemoglobin less than 6.0 g/dl prior to enrolment
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 Rheumatoid Arthritis [RA], Systemic Lupus Erythematosus [SLE] or M. SjÖgren) or a pre-existent dermatologic disorder that worsens in combination with UV (like LE or photosensitive eczema)
10. Presence of clinically significant infection requiring continued therapy, severe diarrhoea or uncontrolled diabetes mellitus that would interfere with the appropriate conduct of the study

Date of first enrolment
01/10/2006

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
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3508 GA

Sponsor information

Organisation
University Medical Center Utrecht (UMCU) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharma B.V.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration