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The effect of ultraviolet radiation on the skin manifestations of patients with dermatomyositis

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2008	Skin and Connective Tissue Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR181

Study information

Scientific Title

Study objectives
To determine the initial cutaneous response after ultraviolet B (UVB) provocation of the skin. Specifically we will determine the trafficking of Langerhans cell, leucocytes and lymphocytes and the expression of matrix metalloproteinases (MMP) in skin lesions and compare these with healthy controls, patients with lupus erythematosus and patients with polymorphic light eruption, for which the results have already been obtained.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, single blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dermatomyositis

Interventions
Phototest protocol for patients with DM:
1. To determine the minimal erythema dose (MED) for UVB, ultraviolet A (UVA), and visible light
2. To determine the clinical aspect of the photo provoked skin lesions
3. To determine the time interval between the start of photo testing and induction of skin lesions until their resolution
4. To record any adverse events

The information thus acquired can be used to advice the patient more specifically on appropriate protection measures that can be taken against environmental UV radiation. Determination of the cellular trafficking in the initial cutaneous inflammation induced by photo provocation in patients with DM. After determination of the MED for UVB a test area of 5 cm

square on the upper back will be exposed to 3 MED UVB. Skin biopsies (4 mm) will be taken of the test area at 0, 24, 48 and 72 hours after one single UVB exposure with 3 MED. These skin biopsies will be compared with those of healthy controls, patients with lupus erythematosus and patients with polymorphic light eruption. The results for these groups have already been obtained.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Determine the initial cutaneous response after UVB provocation of the skin. Specifically we will determine the trafficking of Langerhans cell, leucocytes and lymphocytes and the expression of MMP in skin lesions and compare these with healthy controls, patients with lupus erythematosus and patients with polymorphic light eruption, for which the results have already been obtained.

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/09/2004

Completion date
24/09/2006

Eligibility

Key inclusion criteria
1. Patients with dermatomyositis (DM) that have been diagnosed according to international accepted guidelines (1 - 3)
2. The medication that is used by the patients specifically for DM or other related symptoms will be continued during phototesting
3. The patients should not use corticosteroid creams or sunscreens during phototesting
4. Patients with DM are invited to participate in this study and are included after signed informed consent is obtained

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Key exclusion criteria
Any malignancy for which the patient is treated with cytostatic drugs and/or radiotherapy.

Date of first enrolment
24/09/2004

Date of final enrolment
24/09/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details
PO Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
University/education

Website
http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type

Not defined

Funder Name
Not provided at time of registration

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