

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration