

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

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| <b>Submission date</b><br>20/12/2005   | <b>Recruitment status</b><br>No longer recruiting                | <input type="checkbox"/> Prospectively registered    |
|  |  | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>20/12/2005 | <b>Overall study status</b><br>Completed                         | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>18/07/2008       | <b>Condition category</b><br>Skin and Connective Tissue Diseases | <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

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