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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22361

Source
NTR

Brief title
N/A

Health condition

Dermatomyositis

Sponsors and support

Primary sponsor: Dept of Dermatology/Allergology
University Medical Centre
Heidelberglaan 100, G02.124
3584CX Utrecht
Netherlands
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

In summary, we will 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

N/A

Study description

Background summary

In summary, we will 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.

Study objective

N/A

Study design

N/A

Intervention

In summary, we will use our phototest protocol for patients with DM;

1. To determine the minimal erythema dose (MED) for UVB, UVA, and visible light.

2. To determine the clinical aspect of the photoprovoked skin lesions.

3. To determine the time interval between the start of phototesting 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.

B. Determination of the cellular trafficking in the initial cutaneous inflammation induced by photoprovocation 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with 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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2004
Enrollment:	10
Type:	Actual

Ethics review

Positive opinion

Date:	05-09-2005
Application type:	First submission

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
NTR-new	NL146
NTR-old	NTR181
Other	: N/A
ISRCTN	ISRCTN35411849

Study results