ISRCTN35411849 https://doi.org/10.1186/ISRCTN35411849

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

Contact name
Dr Cornelus J.G. Sanders

Contact details
University Medical Centre
Department of Dermatology/Allergology, G02.124
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
c.sanders@azu.nl

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

Primary study design
Interventional

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

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