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Effects of ultraviolet A1 (UVA1) phototherapy in patients with systemic sclerosis (SSc)

Submission date	Recruitment status	[X] Prospectively registered
07/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/06/2016	Musculoskeletal 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
N/A

Study information

Scientific Title

Effets of high dose UVA1 phototherapy on cutaneous fibrosis and endothelial cell function in patients with systemic sclerosis

Study objectives
One of the characteristic features of systemic sclerosis (SSc) is excessive deposition of collagen within the skin. Such changes are believed to be the results of inappropriate activation of dermal fibroblasts by various inflammatory and pro-fibrotic cytokines, combined with damage to the endothelium. Numerous treatments, some such as immunosuppressive drugs with potentially hazardous side-effects, are currently used with only limited success. Recent pilot studies have reported successful treatment of patients with scleroderma (hard skin) by high dose ultraviolet A1 (UVA1) phototherapy. The hypothesis of this study is high dose UVA1 phototherapy is useful in the treatment of skin fibrosis in patients with SSc through the reduction of collagen deposition and improvement of endothelial functions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Within patient, double blind, sham controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Systemic sclerosis

Interventions
1. Intervention: UVA1 photo-irradiation therapy to the patient's arm
2. Control: sham treatment to the patient's arm

Patients with early stage SSc will receive a total of twenty phototherapy treatments. Both arms will be placed into similar light boxes but only one arm will receive the UVA1 light therapy treatment. Comparisons will be made by measuring elasticity and collagen content of the skin, but also by looking at skin biopsies, blood vessel function and release of various cytokines and expression of markers of scarring tissues in the skin biopsy.

The study will take a total of eight weeks per participant. There will be a total of twenty phototherapy sessions with the duration of treatment at each session being no longer than 50 minutes. This will depend upon the individual and the minimal erythema dose (MED) (the MED is defined as the minimum amount of irradiation at a waveband capable of producing a perceptible erythema) as to how long the phototherapy at each session will take.

Assessments will take place at the start of the study, during the treatment and again two weeks after the final treatment session. The following assessments will be performed:
Visit 1: day 0 - duration: no longer than 3 hours
1. Written consent
2. Medical history
3. Phototesting
4. Skin elasticity
5. Iontophoresis and scanning laser doppler imaging
5. Skin scan
6. Skin biopsy
7. Haematology and biochemistry blood tests
8. Photograph arms

Visit 2: day 6 - duration: no longer than 20 minutes
1. Skin elasticity
2. Skin scan
3. Visual analogue scale
4. 5-point likert scale

Visit 3: day 15 - duration: no longer than 2 hours
1. Skin elasticity
2. Iontophoresis and scanning laser doppler imaging
3. Skin scan
4. Skin biopsy (group 1)
5. Haematology and biochemistry blood tests
6. Visual analogue scale
7. 5-point likert scale

Visit 4: day 21 - duration: no longer than 20 minutes
1. Skin elasticity
2. Skin scan
3. Photograph arms
4. Visual analogue scale
5. 5-point likert scale

Visit 5: 14 days after final treatment - duration: no longer than 2 hours
1. Skin elasticity
2. Iontophoresis and scanning laser doppler imaging
3. Skin scan
4. Skin biopsy (group 2)
5. Haematology and biochemistry blood tests
6. Photograph arms
7. Visual analogue scale
8. 5-point likert scale

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ultraviolet A1 (UVA1) phototherapy

Primary outcome measure
To examine, within subjects, the effects of high dose UVA1 phototherapy in treating patients with SSc. Clinical and laboratory assessments of skin fibrosis, skin blood flow and endothelial cell function will be undertaken.

See interventions for details on when these points will be measured.

Secondary outcome measures
1. Measure the effect of UVA1 phototherapy on skin fibrosis using clinical assessment of the skin. The elasticiy and tethering of the skin and one of the main components of the skin, collagen, will be analysed. The release of various noxious chemicals and expression of markers of scarring tissues will be examined in the skin biopsy.
2. Measure the effect of UVA1 phototherapy on cutaneous blood flow. The ability of the blood vessel to respond to local application of chemicals that are known to increase blood flow, a process called ionotophoresis, will be taken as a measure of the function of the skin blood vessels.
3. Assess the affect of UVA1 phototherapy on the release of various noxious chemicals and expression of markers of scarring tissues in fibroblasts in the laboratory

See interventions for details on when these points will be measured.

Overall study start date
01/04/2008

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. Patients with SSc (both limited and diffuse disease pattern) as diagnosed according to the American College of Rheumatology preliminary classification criteria for this condition
2. SSc patients with cutaneous manifestations
3. SSc patients whose diagnosis was made within the previous 3 years
4. SSc patients who are capable of providing a written informed consent
5. Patients of either sex and aged 18 or above will be recruited

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patients who have received phototherapy in the previous three months
2. Patients who have been started on immunosuppressive treatment within the previous 6 months
3. Patients with localised or generalised morphoea
4. Patients with other sclerodermas other than that associated with SSc. Examples of other forms of sclerodermas include occupational scleroderma (e.g. vinyl chloride disease), scleroporphyria (a generalised morphoea picture arising due to porphyria cutanea tarda), acrosclerosis atrophicans (a late feature of some patterns of Lyme borreliosis, a tick-borne spirochaetal infection) and nephrogenic fibrosing dermopathy.
5. Pregnant or breastfeeding women
6. Subjects who are 18 years or under

Date of first enrolment
01/04/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University Division of Medicine & Therapeutics
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Sponsor information

Organisation
University of Dundee (UK)

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Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
University/education

Funder Name
University of Dundee (UK) - University Division of Medicine & Therapeutics Research Fund

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