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Iontophoresis as a possible therapy for digital ischaemia

Submission date	Recruitment status
12/05/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
29/07/2013	Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English Summary
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
6621

Study information

Scientific Title
Iontophoresis as a possible therapy for digital ischaemia - preliminary studies in patients with scleroderma spectrum disorders

Acronym
Iontophoresis Study

Study hypothesis
Six patients with scleroderma (SSc) spectrum disorder, and associated digital ischaemia and/or ulceration, who are in hospital to receive intravenous (IV) vasodilation therapy, will be recruited for the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salford and Trafford Research Ethics Committee approved (ref: 04/Q1404/209)

Study design
Single centre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Tonia.Moore@srft.nhs.uk to request a patient information sheet

Condition
Topic: Skin, Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics), Skin (all Subtopics); Disease: Musculoskeletal, Dermatology

Interventions
Iontophoresis will be delivered over the whole finger. The iontophoresis dose will be 200 uA of 0.5% NaNP (diluted by volume in distilled water) for 5 mins, 4 times a day (but this will be reduced if troublesome tingling/paraesthesis occurs with this schedule) for 5 days (the duration of the iloprost treatment). The NaNP iontophoresis will be ADDITIONAL to the IV prostanoid therapy for which the patient was admitted.

Follow-up length: 0 months
Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Increase in perfusion; one laser Doppler image will be taken before and after treatment on days 1, 2 and 5 where possible.

Secondary outcome measures
1. Modified Scleroderma Health Assessment Questionnaire (SHAQ); these will be filled out by patients at the start and end of the 5 day treatment period
2. Patient opinion, measured at the end of the 5 day treatment period

Overall study start date
01/09/2006

Overall study end date
30/09/2010

Eligibility

Participant inclusion criteria
1. A diagnosis of SSc (or of another scleroderma-spectrum disorder)
2. Severe digital ischaemia
3. Digital ulceration severe enough to require hospitalisation for intravenous prostanoid therapy
4. Aged 18 - 80 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 6; UK sample size: 6

Participant exclusion criteria
1. Aged less than 18 or greater than 80 years
2. Pregnancy

Recruitment start date
01/09/2006

Recruitment end date
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Sciences Building
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

Sponsor details
Rheumatic Diseases Centre, CSB
Hope Hospital
Stott Lane
Salford
England
United Kingdom
M6 8HD

Sponsor type
Hospital/treatment centre

Website
http://www.srht.nhs.uk

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Research organisation

Funder Name
Raynaud's and Scleroderma Association (UK)

Alternative Name(s)
RSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2008		Yes	No