

Iontophoresis as a possible therapy for digital ischaemia

Submission date

12/05/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

12/05/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

29/07/2013

Condition category

Skin and Connective Tissue Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 objectives

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

Health condition(s) or problem(s) studied

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/paraesthesia 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

Completion date

30/09/2010

Eligibility

Key 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

Key exclusion criteria

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

Date of first enrolment

01/09/2006

Date of final enrolment

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