

# Iontophoresis as a possible therapy for digital ischaemia

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/07/2013	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**  
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](mailto: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?
<a href="#">Results article</a>	results	01/01/2008		Yes	No