# PISCES: Pressure and pain In SCleroderma an Evaluation of a Simple intervention

Submission date Recruitment status [X] Prospectively registered 25/03/2010 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 19/04/2010 Completed [X] Results [ ] Individual participant data **Last Edited** Condition category 04/10/2018 Musculoskeletal Diseases

## Plain English summary of protocol

Not provided at time of registration

## **Contact information**

### Type(s)

Scientific

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## Additional identifiers

## Protocol serial number

PISCES2010

# Study information

#### Scientific Title

A multicentre randomised controlled trial to determine the efficacy of a simple pressurerelieving insole compared to a sham insole

#### **Acronym**

**PISCES** 

#### **Study objectives**

Scleroderma (SSc) is an autoimmune rheumatic disease characterised by excessive collagen production resulting in microvascular and macrovascular damage, fibrosis of the skin and internal organs. (Della Rossa et al. 2001; Balbir-Gurman et al. 2002).

Foot problems in SSc have been reported to be common and disabling (Sari-Kouzel et al. 2001, La Montagna, et al. 2002). Foot symptoms associated with SSc include: Raynauds phenomenon, necrotizing Raynauds leading to apical digital ulceration, subcutaneous calcinosis, skin thickening, callus formation, tendonitis (anterior and posterior muscle tendons and flexor-extensor toe tendons), foot ulcers, joint space narrowing, bone demineralization, joint subluxation, joint margin erosions and degenerative changes (Sari-Kouzel et al. 2001, La Montagna et al. 2002). Arthropathy is also common in patients with SSc and is a major determinant of disability (La Mongtana et al. 2005).

#### **Hypothesis:**

Foot pain and foot-related health status in people with SSc can be improved through provision of a simple pressure-relieving insole.

### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The trial will be reviewed by the Leeds West Research Ethics committee on 14/05/2010

### Study design

Pragmatic phase III multicentre randomised placebo controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Scleroderma

#### **Interventions**

The active intervention to be tested is a commercially available pressure-relieving insole. The insoles are composed of 4 mm thick polyurethane cushioning and a 2 mm Plastazote layer, which provides cushioning and thermal insulation. While a standard insole is being used for consistency, this is a relatively generic product and the insole being evaluated would represent a variety of similar products available on the open market.

The sham intervention used in the control arm will consist of a 1 mm thick regenerated leatherboard base with a thin (<1 mm) plastazote cover. The sham intervention will provide a physical insole similar in appearance to the active intervention insole (will look identical to the intervention insole once placed in the participants shoes), but will not offer cushioning or alter the plantar foot pressures and has minimal thermal insulating properties.

#### Intervention Type

Other

#### **Phase**

Phase III

## Primary outcome(s)

Change in Visual Analogue Scale (VAS) foot pain from the Foot Function Index (FFI) between baseline and 12 weeks.

VAS foot pain will be compared between treatment groups using Analysis of Covariance adjusting for baseline pain score, centre and gender. Model assumptions will be checked and if found to be violated data will be transformed prior to analysis or a non-parametric analysis method will be used. Summary statistics of the foot pain score at baseline and week 12 will be presented for the overall pain component as well as each individual pain question.

#### Key secondary outcome(s))

1. Manchester Foot Pain and Disability Questionnaire:

The change in Manchester Foot Pain and Disability Questionnaire score per patient between baseline and 12 weeks for the pain and ambulation sub-scales (although not the other two scales as they only contain two items each) will be compared between treatment groups using Analysis of Covariance adjusting for baseline score, centre and gender. Summary statistics for the total score and for each component at baseline and week 12 will be presented.

2. Scleroderma Health Assessment Questionnaire (S-HAQ):

The overall HAQ score will be presented as an average score across all domains (scores ranging from 0, no impairment in function to 3, maximal impairment of function). Change in HAQ score between baseline and 12 weeks will be computed and compared between groups using Analysis of Covariance, adjusting for centre, gender, baseline HAQ score and age. Assumptions of the modelling will be checked and appropriate non-parametric analyses used if assumptions do not hold.

3. Scleroderma-specific VAS (relating to overall disease activity, Raynauds phenomenon, finger ulcers, breathing, and intestinal problems) will be summarised and analysed separately. Change in VAS score between baseline and 12 weeks will be computed and compared between groups using Analysis of Covariance, adjusting for centre, gender, age and baseline VAS. Assumptions of the modelling will be checked and appropriate non-parametric analyses used if assumptions do not hold.

### Completion date

31/12/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Consultant diagnosis of SSc or a positive diagnosis of SSc (ARA/ACR 1980 criteria) defined by:
- 1.1. Major criterion:

Proximal diffuse (truncal) sclerosis (skin tightness, thickening, non-pitting induration)

- 1.2. Minor criterion:
- 1.2.1. Sclerodactyly (only fingers and/or toes)
- 1.2.2. Digital pitting scars or loss of substance of the digital finger pads (pulp loss)

- 1.2.3. Bilateral basilar pulmonary fibrosis
- 1.2.4. The patient should fulfil the major criterion or two of the three minor criteria unless a consultant diagnosis has been made. Raynaud's phenomenon is observed in 90-98 % of SSc patients.
- 2. Patient-reported plantar foot pain
- 3. Willing and able to comply with the treatment schedule for 12 weeks
- 4. Able to provide written informed consent to participate in the study
- 5. Age ≥ 18 years

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Disease overlap syndromes (overlap with inflammatory arthritis [IA]/rheumatoid arthritis [RA])
- 2. History of any lower limb bone or joint orthopaedic surgery within the past 12 months
- 3. Diagnosis of diabetes
- 4. A loss of protective sensation on the plantar surface of the foot
- 5. Current use of prescribed or over-the-counter contoured or made-to-measure insoles/orthoses
- 6. History of any clinically significant disease or major disorder that in the opinion of the treating clinician or Chief Investigator would not be conducive to study participation

#### Date of first enrolment

01/07/2010

#### Date of final enrolment

31/12/2011

## Locations

#### Countries of recruitment

United Kingdom

England

## Study participating centre The University of Leeds LEEDS

# Sponsor information

### Organisation

University of Leeds (UK)

#### **ROR**

https://ror.org/024mrxd33

## Funder(s)

#### Funder type

Charity

#### **Funder Name**

Arthritis Research UK (UK) - (formally Arthritis Research Campaign [ARC])

## Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type Details
Results article results

Date created Date added Peer reviewed? Patient-facing?

01/06/2013

<u>Protocol article</u>	protocol	06/02/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes