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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
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PISCES2010

Study information

Scientific Title
A multicentre randomised controlled trial to determine the efficacy of a simple pressure-relieving 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/07/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 140 patients with SSc will be recruited over a period of 18 months.

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
England

United Kingdom

Study participating centre
The University of Leeds
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Sponsor information

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Sponsor type
University/education

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

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?
Protocol article	protocol	06/02/2012		Yes	No
Results article	results	01/06/2013		Yes	No