

Causes and treatments in mechanically induced foot pain

Submission date 30/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/09/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
6050

Study information

Scientific Title
Pathological processes and candidate interventions in mechanically induced foot pain: a single centre randomised interventional screening and treatment trial

Acronym

PainFoot

Study objectives

Foot pain in healthy individuals is often associated with poor movement and function of the lower limbs. Abnormal function in other joints such as the knees and hands has been shown to be associated with early magnetic resonance imaging (MRI) abnormalities, which in turn can be a precursor to osteoarthritis. The associations between foot pain, patterns of bone/joint swelling on MRI and joint movement analysis have not been previously explored. This study aims to investigate the effects of in-shoe orthotic devices; commonly used to treat foot pain, upon foot movement, symptoms and MRI findings.

Objectives:

1. To identify using MRI, patterns of altered metabolism in the bones of the midfoot and to explore the relationship of these changes to movement characteristics associated with pain in the arch of the foot
2. Investigate the potential for orthoses to change systematically; foot mechanical function, pain and patterns of altered bone metabolism

Design:

Proof of concept study and clinical investigation with a laboratory and imaging component.

Treatment groups:

1. Functional foot orthoses intended to systematically alter foot function
2. Inert cushioning orthoses known to exert minimal effect on the intrinsic function of the foot

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. South Humber Research Ethics Committee, 17/03/2009
2. Amendments approved by Leeds West Research Ethics Committee, 02/06/2010, ref: 09/H1305/10

Study design

Single-centre randomised interventional screening and treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

Random allocation to one of the following:

1. Functional foot orthoses intended to systematically alter foot function
2. Inert cushioning orthoses known to exert minimal effect on the intrinsic function of the foot

Follow-up length: 3 months
Study entry: registration and one or more randomisations

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Pain scores (VAS) measured at baseline, 6 weeks and 12 weeks

Key secondary outcome(s)

Measured at baseline, 6 weeks and 12 weeks:

1. Modified Manchester Foot Pain and Disability Questionnaire
2. MRI semi-quantitative and quantitative scores
3. Multi-segment foot kinematics

Completion date

01/01/2011

Eligibility

Key inclusion criteria

Both groups:

1. Participants aged 18 years and over
2. Both male and female
3. Able to understand and provide informed consent

Foot pain group:

3. History of foot pain when weight bearing between 3 and 18 months duration
4. Pain located in the midfoot region
5. Type of pain considered consistent with pain of mechanical origin by an experienced musculoskeletal specialist podiatrist

Comparative healthy pain free group:

6. No history of foot pain in the last 24 months
7. Able to walk for 30 minutes without pain or discomfort in any other lower limb joints

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Foot pain group:

1. Established OA of the midfoot region
2. Foot surgery in the last 12 months
3. Localised plantar heel pain typical of plantar fasciitis
4. Foot pain typical of undiagnosed inflammatory arthritis inflamed ankle joint complex, bursitis, tenosynovitis, enthesitis
5. A medical history of unstable diabetes mellitus or diabetic complications
6. A medical history of peripheral arterial disease
7. A medical history of systemic inflammatory disease
8. Known pregnancy
9. A medical history of kidney disease
10. A medical history of organ transplantation
11. A patient fitted with a pacemaker or any other implant contra-indicated for magnetic resonance imaging (MRI) scanning
12. Recent heart bypass surgery in the last 6 months
13. Currently wearing in-shoe orthoses device
14. A medical history of neurological disorders or positive clinical findings of pedal sensory neuropathy

Comparative healthy pain free group:

15. A medical history of unstable diabetes mellitus or diabetic complications
16. A medical history of peripheral arterial disease
17. A medical history of systemic inflammatory disease
18. Known pregnancy
19. A medical history of kidney disease
20. A medical history of organ transplantation
21. A patient fitted with a pacemaker or any other implant contra-indicated for MRI scanning

Date of first enrolment

29/05/2009

Date of final enrolment

01/01/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Chapel Allerton Hospital
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation

University of Leeds (UK)

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research UK (UK)

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	Date created	Date added	Peer reviewed?	Patient-facing?
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[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes