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Causes and treatments in mechanically induced foot pain

Submission date	Recruitment status	[ ] Prospectively registered
30/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/09/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.leeds.ac.uk/medicine/FASTER/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
29/05/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 120, UK sample size: 120

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 magentic 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
England

United Kingdom

Study participating centre
Chapel Allerton Hospital
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

Website

http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

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

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