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Effects of shoe type on ankle sprain recovery

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2008	Injury, Occupational Diseases, Poisoning	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0013180317

Study information

Scientific Title

Study objectives
Does the type of shoe worn in the early period early after ankle sprain influence recovery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Injury, Occupational Diseases, Poisoning: Ankle sprain

Interventions
A randomised controlled trial involving participants being assigned control shoe (rocker) or experimental shoe (MDT).
Measurements will be taken before and after to assess the difference. Subjects will be given instructions and diary for 1 week before returning for testing.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Self-assessment of ankle function via questionnaire

Secondary outcome measures

Not provided at time of registration

Overall study start date
18/05/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. 2 groups of 20 individuals contacted within 3 days of presenting to Guy's Minor Injury Unit with sprained ankle
2. Aged 18-60 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. Subjects with abnormal sensory problems in the thigh and lower leg, subjects with any neurological problem affecting their balance and subjects will be excluded.
2. Patients who have had musculoskeletal or neurological problem affecting their legs or low back which required medical attention in the last 6 months will also be excluded.

Date of first enrolment
18/05/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Applied Biomedical Research (CABR)
London
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Guy's and St. Thomas' NHS Foundation Trust (UK), Own account NHS R&D Support Funding

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