Effects of shoe type on ankle sprain recovery

Submission date 28/09/2007	Recruitment status No longer recruiting	Prospectively registered
		☐ 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

Contact name

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Contact details

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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

Study participating centre
Centre for Applied Biomedical Research (CABR)
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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 summaryNot provided at time of registration