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Rocker soles for the treatment of intermittent claudication

Submission date	Recruitment status	[X] Prospectively registered
26/05/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/06/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/03/2017	Musculoskeletal Diseases	[ ] 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
Version 1

Study information

Scientific Title
The efficacy of rocker soles in alleviating the symptoms of intermittent claudication: a randomised controlled trial

Acronym
Rocker trial

Study objectives
Intermittent claudication is a vascular disease affecting the lower limbs. Sudden pain is normally experienced in the calf muscles which forces subjects with the condition to eventually stop walking. After a short period of rest, they are able to start walking again until the pain again becomes intolerable.

Hypothesis:
That a specifically-designed rocker sole profile may help alleviate the painful symptoms of intermittent claudication in older subjects. The intervention will be through the addition of a specifically-designed rocker sole profile added to the base of stock therapeutic shoes. This profile has been designed and tested using 12 healthy subjects during gait laboratory testing and it has been demonstrated that it statistically significantly reduces the sagittal plane power absorbed and generated at the ankle during walking. It is hoped that this reduction will translate into improved symptoms for patients with intermittent claudication by reducing the work done by the muscles acting across the ankle joint during stance phase of gait when walking with the rocker sole profile added to their shoes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration - submission pending

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Intermittent claudication

Interventions
Volunteer claudicants will be recruited onto the study via attendance at the Lifestyle Management Clinic in the Vascular Department at Wirral University Teaching Hospitals NHS Trust, Wirral, England, UK.

The intervention group will wear a shoe adapted with a rocker profile for a two-week period. The control group will be given an un-adapted pair of shoes to wear, which will be exactly the same style as the intervention group in order to eliminate footwear design factors between the two groups. The intervention group will wear the same shoes as the control group during the two-week trial period but with the rocker sole profile added also. The control group will therefore not receive any rocker sole type intervention but will wear a pair of shoes supplied for the trial which they are free to keep at the end of the two weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The following hospital-based walking trials will be held immediately before and after the two-week home trials:
1. Pain-free walking distance (PFWD) to the sudden onset of calf claudication pain
2. Overall intensity of calf claudication pain whilst claudicating
3. Maximum walking distance (MWD) before having to stop due to the intensity of the calf pain
4. Walking speed, step length and cadence

Secondary outcome measures
Quality of life (QOL) indicators using the intermittent claudication questionnaire (ICQ) before and after the two-week trial. It is anticipated that a future larger trial will be needed to provide statistically significant differences to QOL indicators, but this trial will give an indication and will inform the total number of recruits required in a subsequent trial study.

Overall study start date
01/01/2009

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Both males and females, over 18 years of age. There are no upper age limits
2. Those who have been diagnosed with stabilised intermittent claudication in one or both calf muscles

3. Ankle brachial pressure index of 0.8 or less
4. Those who have a maximum walking distance of between 10-300 m before having to stop walking due to their calf pain which is not being improved by other conservative interventions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 (60 per randomised group)

Key exclusion criteria
Subjects with a history of lower limb joint replacement, cerebrovascular accident (CVA), or any orthopaedic or neurological impairment which adversely affects their gait or negates the fitting of stock therapeutic shoes

Date of first enrolment
01/01/2009

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Salford
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Sponsor information

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Sponsor type
University/education

Website
http://www.salford.ac.uk

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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