ISRCTN79785265 https://doi.org/10.1186/ISRCTN79785265

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Salford
Salford
United Kingdom
M6 6PU

Sponsor information

Organisation
University of Salford (UK)

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes