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Clinical trial of insoles for heel pain

Submission date 23/04/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/07/2008	**Overall study status** Completed	
Last Edited 06/05/2016	**Condition category** Musculoskeletal Diseases	

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
CT222

Study information

Scientific Title
A randomized controlled trial to evaluate the effectiveness of insoles to treat plantar heel pain

Acronym
HELP Trial

Study objectives
A functional insole and a silicon gel heel pad will each produce greater improvements in heel pain compared to a sham control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University of Salford, 23/03/2008, ref: 07/054

Study design
Randomised, single-blinded (subjects blinded), single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Plantar heel pain

Interventions
The participants will be randomly allocated to the following three arms:

1. Intervention group 1: Orthaheel® regular. This is a 3/4 length insole with arch shape which is positioned under the heel and the middle of the foot. It is inserted into shoes and worn daily.
2. Intervention group 2: Orthaheel® gel heel pad. This is a silicon gel based insole which is positioned under the heel. It is inserted into shoes and worn daily.
3. Sham control group: Flat 3 mm soft insole with fabric cover

Subjects are blinded to their group allocation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Foot pain
2. Foot health related function

Foot pain will be measured primarily using a 0-10 visual analogue scale. The Foot Health Status Questionnaire (FHSQ) will be used to provide categorical assessment of pain and foot health related function.

Primary timepoint of interest: 4 weeks

Secondary outcome measures
1. Use of insoles (in time)
2. Foot pain at 3, 6 and 12 months (see Primary outcome measures for details)
3. Foot health related function at 3, 6 and 12 months (see Primary outcome measures for details)

Overall study start date
28/03/2008

Completion date
31/07/2009

Eligibility

Key inclusion criteria
1. Male or female participants between the ages of 18 and 65 years old
2. Participants with self-reported plantar heel pain with a minimum of 4 weeks duration
3. Self-reported plantar heel pain who score at least 40 mm on a 100 mm visual analogue scale (VAS) for pain
4. Participants with plantar heel pain in the 2 days prior to recruitment
5. Participants who agree to wear the insoles provided for at least 4 hours each day
6. Participants who give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Participants reporting acute injury to the foot at the onset of the plantar heel pain
2. Participants with posterior or medial/lateral heel pain or any secondary pain elsewhere in the foot since the onset of plantar heel pain
3. Participants with significant musculo-skeletal disease diagnosed such as rheumatoid arthritis, hip, knee or back pain
4. Participants with sensory or motor function disease such as diabetes
5. Participants who are pregnant or breast-feeding
6. Participants who have received or self-administered treatment for the heel pain in the previous 4 weeks
7. Participants who have received corticosteroid injection therapy in the heel in the previous 3 months
8. Participants that were previously in this study
9. Participants that were in another study within the last 3 months

Date of first enrolment
28/03/2008

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Director
Salford
United Kingdom
M6 6PU

Sponsor information

Organisation
SSL International (UK)

Sponsor details
SSL International Plc
Venus, 1 Old Park Lane

Trafford Park
Urmston
Manchester
United Kingdom
M41 7HA

Sponsor type
Industry

Website
http://www.ssl-international.com

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type
Industry

Funder Name
SSL International Ltd (UK)

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