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# Clinical trial of insoles for heel pain

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