

# Clinical trial of insoles for heel pain

<b>Submission date</b> 23/04/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/07/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/05/2016	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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

**Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

**Director**

Salford

United Kingdom

M6 6PU

## **Sponsor information**

**Organisation**

SSL International (UK)

**ROR**

<https://ror.org/01g87hr29>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

SSL International Ltd (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration