

# Feasibility study to evaluate the clinical and cost effectiveness of foot orthoses in the management of plantar heel pain

<b>Submission date</b> 18/12/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/12/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/10/2007	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Keith Rome

**Contact details**  
University of Teesside  
School of Health and Social Care  
Middlesbrough  
United Kingdom  
TS1 3BA  
+44 (0)1642 384977  
K.Rome@tees.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
RRC300/SG

# Study information

## Scientific Title

## Study objectives

Not provided at time of registration

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Plantar heel pain

## Interventions

Two types of foot orthoses (based on costs and function) were measured at baseline, 4 and 8 weeks using general (EQ5D), specific (Foot Health Status Questionnaire) outcome measures together with an economic questionnaire

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Not provided at time of registration

## Secondary outcome measures

Not provided at time of registration

**Overall study start date**

01/01/2001

**Completion date**

01/01/2002

## **Eligibility**

**Key inclusion criteria**

48 patients clinically diagnosed with plantar heel pain. The inclusion criteria included the following:

1. Unilateral plantar heel pain of at least 2-months duration
2. A history of night-time or early morning pain, which decreases after walking, and/or increases after exercise or prolonged periods of standing
3. Heel pain severe enough to either cause a reduction in physical activity, a visit to a health professional, or the use of medication
4. Good general health

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

48

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

01/01/2002

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**University of Teesside**  
Middlesbrough  
United Kingdom  
TS1 3BA

## **Sponsor information**

### **Organisation**

North Tyneside AHA Trust Research Unit (UK)

### **Sponsor details**

North Tyneside General Hospital  
Research Support Unit  
Rake Lane  
North Shields  
England  
United Kingdom  
NE29 8NH

### **Sponsor type**

Hospital/treatment centre

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Department of Health (UK) - Directorate of Health & Social Care

## **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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/05/2004		Yes	No