Evaluating a novel semi-rigid casted slipper in diabetic ischaemic foot ulcers

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
15/10/2014	Nutritional, Metabolic, Endocrine	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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0155184582

Study information

Scientific Title

Study objectives

Is the application of semi-rigid coated slippers using soft cast materials, safe and effective in healing ulcers in vulnerable, at risk, ischaemic feet in people with diabetes?

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

Nutritional, Metabolic, Endocrine: Diabetic foot

Interventions

Slipper vs standard treatment

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Ulcer size and patient-focused outcomes

Secondary outcome measures

Patient satisfaction and quality of life

Overall study start date

01/10/2006

Completion date

01/10/2007

Eligibility

Key inclusion criteria

Patients with diabetic ischaemic foot

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of General Medicine

Manchester United Kingdom M8 5RB

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Pennine Acute Hospitals NHS Trust (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