

SSHOES Diabetic Footwear

Submission date 19/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/04/2017	Condition category Nutritional, Metabolic, Endocrine	<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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8619

Study information

Scientific Title

A multicentre non-randomised interventional trial of diabetic footwear in the prevention of foot ulceration

Acronym

DRN 475

Study objectives

The aim of this study is to investigate the effect of four separate footwear design parameters which characterise a rocker shoe in order to develop a system which allows the best design, i.e. the one which minimises pressure, to be predicted from a simple biomechanical assessment of barefoot walking.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North West 8 Research Ethics committee - Greater Manchester East, 05/07/2010, ref: 10/H1013 /32

Study design

Multicentre non-randomised interventional trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

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

Topic: Diabetes Research Network; Subtopic: Both; Disease: Diabetic foot

Interventions

The aim is to measure in-shoe pressures in many different types of footwear in a lab for a range of patients. With this information, we want to develop a system for prescribing bespoke footwear (i.e., footwear which minimises pressure). Patients do not undergo any treatment.

Study Entry: registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Foot pressure after wearing the footwear for 5 minutes under laboratory conditions

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/06/2010

Completion date

01/08/2012

Eligibility

Key inclusion criteria

1. Have been diagnosed with diabetes at least 6 months previously (diabetic cohort only)
2. Be between 18 and 65 years, either sex
3. Be able to the University of Salford three times
4. Be able to walk for 2 - 5 minutes barefoot and in different shoes over 1.5 - 2 hours
5. Be able to understand both written and spoken English

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 100; UK sample size: 100

Key exclusion criteria

1. Currently suffering with any form of ulceration or other foot condition resulting from diabetes
2. Have a major foot deformity sufficient to limit activity
3. Suffering any disorder with affects balance or mobility and/or a history of falls

Date of first enrolment

01/06/2010

Date of final enrolment

01/08/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Salford

Salford

United Kingdom

M6 6PU

Sponsor information

Organisation

Salford Royal NHS Foundation Trust (UK)

Sponsor details

c/o Dr Rachel Georgiou

NHS Salford Research and Development

Clinical Sciences Building

Stott Lane

Salford

England

United Kingdom

M6 8HD

Sponsor type

Hospital/treatment centre

Website

<http://www.srht.nhs.uk/>

ROR

<https://ror.org/019j78370>

Funder(s)

Funder type

Government

Funder Name

European Union (EU) (Belgium) - Seventh Framework Programme (FP7)

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