

SSHOES Diabetic Footwear

Submission date 19/08/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 19/08/2010	Overall study status Completed	☐ Protocol
Last Edited 06/04/2017	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre non-randomised interventional trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre

University of Salford

Salford

United Kingdom

M6 6PU

Sponsor information

Organisation

Salford Royal NHS Foundation Trust (UK)

ROR

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

Funder(s)**Funder type**

Government

Funder Name

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

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration