SSHOES Diabetic Footwear

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

Dr Stephen Preece

Contact details

University of Salford Brian Blatchford Building Salford United Kingdom M6 6PU

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

Study design

Multicentre non-randomised interventional trial

Primary study design

Interventional

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

Αll

Kev 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

Study outputs

Output type **Details** Date created Date added Peer reviewed? Patient-facing? Participant information sheet 11/11/2025 11/11/2025 No

Participant information sheet Yes