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Comparison of insoles prescribed for diabetic patients with and without pedobarograph data

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/05/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol Version 1.3 (19/12/2006)

Study information

Scientific Title
Comparison of insoles prescribed for diabetic patients with and without pedobarograph data

Study objectives
Participants who have custom made insoles based on a pedobarograph assessment will have a reduced incidence of plantar ulceration over a two year period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Nottinghamshire Local Research Ethics Committee, 05/04/2007, ref: 06/Q2402/72

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Currently patients are issued with a poron insole designed according to the clinical examination of the foot. Patients who fit the inclusion criteria will be given information regarding the study at their initial appointment and will be asked to consent to be involved. They will receive a baseline assessment, which will include a photograph being taken of the plantar aspect of the feet. This photograph will be taken before debriding the callus. They will then be randomly placed into one of two groups:

Group A: will undergo a pedobarograph assessment and will receive a custom-made poron insole
Group B: will receive an insole assessed following current clinical practice.

Information will also be collected about whether the participant has neuropathy, ischaemia or deformity. If a participant develops a callus that involves a change of insole or an ulcer at any

point in the two years, then they would have met the failure criteria of the project. Participants will be instructed at the start of the study to return to podiatry if they develop a callus (or other foot problems). The date of the callus or ulceration causing change of insole design being identified by podiatry will be recorded and used in the study. If the participant is withdrawn from the study for other reasons these will be recorded.

Participants will attend an annual review and at this time if there is no callus or ulceration requiring a change of insole design a new insole of the same design will be issued. A final review of participants remaining in the study will be performed after two years. At any follow up appointments the digital photograph from the initial assessment will be used as a reference to identify changes in the plantar surface of the foot.

Data will be collected from both groups of participants over two years and following this the average time to callus/ulceration in the two groups will be analysed. There will also be an analysis of specific groups of patients, e.g., those with neuropathy, show a more significant difference between the two groups. The reasons for participants being withdrawn from the study will also be analysed. The patients will all be recruited in the first year and then followed up over two years from their entry date into the study. Kaplien-Meier survival curves will be plotted for the two groups.

Intervention Type
Device

Primary outcome measure
To evaluate whether custom made insoles for diabetic patients which are guided in design by the pedobarograph data are more effective in reducing skin damage/callus/ulceration than those assessed via current clinical practice.

Secondary outcome measures
To evaluate how neuropathy, ischaemia and deformity affect the outcome of using an insole.

Overall study start date
01/01/2007

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Able to walk a minimum of five metres unaided
2. New referral to podiatry
3. Presenting with plantar callus at initial podiatry assessment
4. No previous insole treatment
5. Aged greater than 18 years old

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
402

Key exclusion criteria
1. Unable to walk a minimum of five metres unaided
2. Current ulceration
3. Previous insole treatment
4. Non-diabetes related medical problems affecting the lower limbs
5. Lower limb amputation at any level
6. Unclear diabetes diagnosis
7. Congenital foot deformities
8. Charcot foot changes
9. Previous foot or ankle surgery

Date of first enrolment
01/01/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gait and Movement Laboratory
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Derby Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Office
Medical School
Derby City General Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE

Sponsor type
Hospital/treatment centre

Website
http://www.derbyhospitals.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
Derby Hospitals NHS Foundation Trust (UK) - Grant Scheme

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