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Foot ulcer treatment with the PulseFlowDF Boot

Submission date	Recruitment status	[X] Prospectively registered
22/11/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/12/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/06/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Foot ulcerations are non-healing wounds that are common in people with diabetes, and can lead to infection and amputation. A new boot is being tested that may help protect the foot and which also aims to improve the blood flow to the ulcer. The aim of this study is to compare this new boot to a standard boot as a treatment for foot ulceration in people with diabetes.

Who can participate?
Patients aged over 17 with diabetic foot ulcers

What does the study involve?
Participants are randomly allocated to wear either the new boot or the standard boot for 3 months. During the 3 months participants receive standard care (dressings) and are also asked to attend a longer appointment once a month to complete questionnaires and undergo foot temperature and pressure measurements.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part. It is not know whether one boot is better than the other, but this study will attempt to find out and this may help people in future. All participants will be closely monitored during the study and any complications of the foot ulcer will be addressed promptly.

Where is the study run from?
Salford Royal Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2017 to March 2018

Who is funding the study?
Pulse Flow Technologies (UK)

Who is the main contact?
Dr Jill Halstead-Rastrick

Contact information

Type(s)
Public

Contact name
Dr Jill Halstead-Rastrick

Contact details
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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
A feasibility study to assess the effect of the PulseFlowDF in the treatment of diabetic foot ulcers

Acronym
PFDF

Study objectives
This feasibility study will examine the effect of wearing the PulseFlowDF, compared to standard orthotic device, as a treatment for foot ulceration in people with diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised feasibility study

Study type(s)
Treatment

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

Interventions
All the participants will be asked to participate in the study for 3 months during which they will be asked to use the allocated treatment for 3 months.

Random allocation of participants to each treatment arm will be assigned using a random numbers table. The order of allocation in each group will follow even and odd numbers as they appear in the table to ensure unbiased allocation. Concealment of the randomisation will be maintained by sealed opaque envelopes; these will be produced by the blinded research assistant for each participant.

Intervention treatment:
PulseFlowDF is a non-invasive treatment for diabetic foot ulcers that has a novel technology which attempts to address the complexity of ulcer healing through increased blood flow, pressure reduction and maximisation of compliance. In several clinical trials it has also been shown that total contact casting can improve healing in neuropathic foot ulcerations. For those that have circulation (vascular) impairment this approach is limited and orthotic devices (walkers) are not always used constantly. Currently, there is no technology that attempts to resolve this. In addition, PulseFlowDF solves the step-down issue, as the boot can be used as a shoe, saving the clinical departments further costs for footwear to potentially prevent ulcer re-occurrence.

Comparator treatment:
We propose to use a below knee Aircast Air Select Standard boot as it is a widely used orthotic device that can immobilise the leg and foot. This boot is widely available on the NHS and is used in pressure reduction for people with foot ulcers.

Intervention Type
Device

Primary outcome(s)
Foot ulcer size, measured at baseline, 4, 8 and 12 weeks

Key secondary outcome(s)
1. Health status, measured with the EQ-5D questionnaire at baseline and 12 weeks
2. Walking impairment, measured with the Walking Impairment Questionnaire at baseline and 12 weeks
3. Thermal image analysis at baseline, 4, 8 and 12 weeks
4. Foot pressure, measured using Tekscan in-shoe plantar pressure measurement at baseline and 3 months
5. Adherence to boots assessed at 4, 8 and 12 weeks

Completion date
01/03/2018

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. >17 years of age
2. Consultant or GP diagnosis of diabetes mellitus (type I or II) documented on the electronic patient record with HbA1C greater than 48mmol/mol recorded in the last 6 months
3. Controlled diabetes as defined as an HbA1c of 86mm/mol (11%) in the last 3 months
4. Foot ulcers (defined by the University Texas wound Classification grades 1A, 1B, 1C, 2A, 2B, 2C) and greater than the volume of 30mm3 (as determined by 3D camera) and or minimum length and width of 5mm x 5mm and 2mm depth
5. Foot ulcer (as defined above) with or without mild infection as defined by IDSA as local infection involving only the skin and the subcutaneous tissue (without involvement of deeper tissues and without systemic signs as described below). If erythema, must be >0.5 cm to ≤ 2cm around the ulcer, once all other causes of an inflammatory response of the skin (e.g. trauma, gout, acute Charcot neuro-osteoarthropathy, fracture, thrombosis and venous stasis) are excluded (Lipsky et al. 2012)
6. People with mild peripheral arterial disease defined as the absence of palpable pulses and or monophasic Doppler signals using audio ultrasound evaluation with an ABPI of 0.8 to 0.51 (or if vessels not compressible e.g. ABPI >1.1) an absolute toe pressure of >51mmHg
7. Foot ulcer at any of the following sites:
7.1. First metatarsophalangeal joint (MTPJ) plantar aspect
7.2. 2nd-5th MTPJs
7.3. Heel
7.4. Plantar aspect of toe/s
8. Patients who have undergone lower extremity surgery / amputation may be enrolled into the study subject to the clinical judgement of the investigator
9. Willingness to adhere to standard clinical care for diabetic foot ulcer as per NICE guidelines (CG10, CG 119 NG19) including dressing regime, pressure reduction and clinical review evidenced by medical history
10. Competence to provide informed consent
11. Foot size ranging from 5-13 (UK)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Ulcer on plantar surface of medial longitudinal arch of foot
2. Severe peripheral arterial disease as evidenced by an ABPI of <0.5 (or if vessels not compressible e.g. ABPI >1.1) an absolute toe pressure of <50mmHg
3. Evidence of venous stasis ulcers or ulcers secondary to tropical disease
4. Moderate to severe infection defined by IDSA as local infection (as described above) with erythema >2cm, or involving structures deeper than skin and subcutaneous tissues (e.g. abscess, osteomyelitis, septic arthritis, fasciitis) and no systemic inflammatory response signs: Local

infection (as described above) with the signs of SIRS, as manifested by ≥2 of the following (Lipsky et al. 2012):
4.1. Body temperature >38°C or <36°C
4.2. Heart rate >90 beats/min
4.3. Respiratory rate >20 breaths/min or PaCO2 <32 mmHg
4.4. White blood cell count >12 000 or <4000 cells/µ Lor ≥ 10% immature (band) form
5. Mild infection of a foot ulcer (as defined above) and on <4 weeks antibiotic treatment
6. Acute septic arthritis
7. Acute fractures of the foot including pathological, related to osteomyelitis
8. Active Charcot Neuroarthropathy
9. Cannot tolerate / unwilling to adhere to standard clinical care as evidenced by NICE guidelines, such as pressure reduction (CG10, CG 119)
10. Current treatment with advanced wound therapies (NICE CG 119 1.1.36):
10.1. Grafts
10.2. Pinch grafts
10.3. Dermal substitutes
10.4. Biological wound therapies to stimulate epithelialisation including but not limited to: growth factors, stem cells, skin cell application and Lave
10.5. Oxygen-delivering therapies
10.6. Electro-stimulation devices
10.7. Micro-current devices
10.8. Laser, kinetic devices
10.9. Negative pressure wound therapy
10.10. Hydro-surgical debridement
10.11. Extensive wound debridement as undertaken by orthopaedic and vascular surgeons requiring operative theatre
11. Rigid foot deformity: Restriction of movement at the subtalar joint and/or the midtarsal joint
12. Surgery for lower limb revascularisation in the 3 months
13. People with functioning infrainguinal bypass grafts in situ and that in the opinion of the vascular consultant should not be placed in an orthotic boot
14. Acute heart failure
15. Pregnancy
16. Participation in an interventional study within the last 30 days
17. A history of any clinically significant disease or major disorder that in the opinion of the research officer and or Chief Investigator would not be conducive to study participation

Date of first enrolment
01/01/2017

Date of final enrolment
01/01/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospital NHS Foundation Trust
Salford
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M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Industry

Funder Name
Pulse Flow Technologies

Results and Publications

Individual participant data (IPD) sharing plan
As this is an industrial study access to patient-level data will only be granted to the study sponsor for regulatory reasons.

IPD sharing plan summary
Not expected to be made available