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A proof-of-concept project to provide evidence that PelliTec blister prevention pads can be used safely by people with healed diabetic foot ulcers in multidisciplinary diabetic foot clinics

Submission date
10/08/2021

Recruitment status
No longer recruiting

Registration date
24/09/2021

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
One in four people with diabetes will develop a foot ulcer. Many foot ulcers develop from trauma /excessive pressure from footwear resulting in blisters or small wounds; if these are left untreated an ulcer can form. Prevention is therefore a key strategy, and this can be achieved through a mix of reducing pressure and friction from the foot and regular foot inspections both by the patient and in specialist multidisciplinary foot clinics.
PelliTec pads are circular friction-reducing pads that have a cushioning gel core designed to reduce the risk of developing blisters. The pads are designed to stick to the inside of the footwear, not on the skin. The aims of this study are to:
1. Provide proof of concept that PelliTec pads can be used safely in patients with healed diabetic foot ulcers in multidisciplinary diabetic foot clinics
2. Evaluate the performance and reliability of the PelliTec pads to confirm these are appropriate for reducing pressure in key regions of interest
3. Assess barriers and facilitators to the adoption of medical devices in the management of diabetic foot ulcers

Who can participate?
Patients aged 18 to 80 years old with diabetes and a history of foot ulcers who receive their usual care at Sheffield Teaching Hospitals NHS Foundation Trust

What does the study involve?
Participants will be involved in the study for 12 weeks.

Visit 1 (duration: 2 hours)
Following informed consent, a Doctor will document the participant's medical history, perform a physical examination including standard clinical tests used to check the ability to feel different sensations including vibration and cold, and ask the participant to complete some questionnaires to assess their quality of life (general and foot ulcer related) and activities

related to participating in this study. At this visit a PelliTec pad will be applied to the participant's footwear over the region of the healed ulcer. Finally, the performance of the PelliTec pad will be tested in the laboratory to simulate everyday foot loading. Participants will be asked to perform a series of simple physical tasks (e.g. sitting, standing, and walking on a level surface and up/down a flight of stairs) whilst wearing a different research-grade smart insole.

Visits 2 to 5 (3 weeks apart to coincide with clinic appointments: duration 30 minutes):
These visits will be conducted by a Research Podiatrist. The podiatrist will confirm the participant's diabetic foot ulcer has not recurred at study visit 2 (week 3) and 3 (week 6). If the ulcer recurs during this period, the PelliTec pad will be removed from the footwear, participants will return to treatment in the foot clinic and continue in the study. If the ulcer does not recur, your ulcer will be considered healed for the study, and participants will continue with study visits 4 (week 9; this will be a telephone visit) and 5 (week 12; in clinic). At visits 3 (week 6) and 5 (week 12), participants will be asked to complete the questionnaires again.

Telephone contact
In addition to the study visits, the research team will contact participants every week when not attending the foot clinic to check the use of the PelliTec pads. A telephone interview will also be conducted with participants to seek their opinions on the use of medical devices in people with foot ulcers. This interview will last 30 minutes. Topics that will be covered include the impact of foot disease on daily activities and the use of medical devices to help patients manage/prevent diabetic foot ulcers.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants from this study. In the long term, the potential benefit of this research is to prevent the recurrence of foot ulcers. This study will provide early data on how best to test the PelliTec Pad in clinical practice.
There are no anticipated risks to taking part in this study. This will be the first time this technology will be used in people with healed foot ulcers, but they have been tested by athletes. The researchers will be assessing the safety of using such devices in the present study.

Where is the study run from?
Royal Hallamshire and Northern General Hospitals, part of Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2020 to October 2023

Who is funding the study?
The National Institute of Health Research (NIHR) Surgical MedTech Co-operative with additional funding from Tectores Ltd (the manufacturer of PelliTec pads)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
293766

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49241, IRAS 293766

Study information

Scientific Title
Diabetic foot ulcer prevention study using PelliTec pads

Study objectives
PelliTec blister prevention pads can be used safely by people with healed diabetic foot ulcers in multidisciplinary diabetic foot clinics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2021, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC5@wales.nhs.uk), REC ref: 21/WA/0150

Study design
Non-randomized; Both; Design type: Prevention, Device, Qualitative

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 to request a participant information sheet

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
Population: 12 to 20 patients with healed foot ulcers. Ulcer healing is defined as complete epithelialisation of the original ulcer maintained for 4 weeks and will be confirmed by the research podiatrist.

Setting: Podiatry led foot-clinics at Sheffield Teaching Hospitals NHS Foundation Trust. The Multi-Disciplinary Foot Team clinics see between 30-40 patients (estimate 5 eligible patients) per clinic.

Intervention: 12-week, open labelled study. Total study duration 6 months. Participants will attend a baseline visit followed by four three-weekly visits to coincide with existing clinic appointments. All patients will have the PelliTec pad applied to the inside of their footwear over the area of the healed ulcer. All components of usual foot/podiatry care will be maintained throughout the study.

Visit 1 (Week 0)
The presence of Diabetic Peripheral Neuropathy (DPN) and Loss of Protective Sensation (LOPS) will be confirmed using the Michigan Neuropathy Screening Instrument (MNSI) and 10g monofilament assessment (plantar surface of the ulcerated foot on three sites: hallux, 1st and 5th metatarsal heads).

Patients will be provided with the PelliTec pad which will be applied in their footwear over the region of the healed ulcer.

Patients will undergo laboratory-based testing to ‘simulate’ everyday foot loading. Research-grade pressure insoles [F-Scan System, Tekscan, Boston, USA] will be used to examine a range of everyday activities placing different loading demands on the plantar foot – level-ground walking, stair negotiation, standing and sitting with feet on the floor. The range of activities will be informed based on the team’s experience of using a smart insole system as part of a 4-year

diabetic foot ulcer prevention trial with continuous pressure monitoring. The same physical activities will then BE repeated but on this occasion patients will have the PelliTec pad applied. A series of plantar pressure-based parameters (including peak pressure, pressure-time and aggregated pressure) will be calculated from the research-grade pressure insoles and compared with and without the PelliTec pad.
These laboratory assessments will be performed by Prof. N Reeve's team of biomedical engineers from Manchester Metropolitan University. Biomedical engineers will be present during this visit to perform so of these measurements.
The researchers aim to complete this activity during Visit 1. If this is not possible, they will arrange this assessment during one of the subsequent study visits.

Participants will be asked to complete the study questionnaires (EQ-5D-5L, CWIS, SF-36, CSRI).

Visits 2 to 5 will be 3 weeks apart (+/- 4 days) to Week 12 (Visit 5).
A Research Podiatrist will perform all patient assessments. The diabetic foot ulcer is first confirmed to have remained healed by a review after 3 weeks (+/- 4 days) and 6 weeks (+/- 4 days). If the ulcer recurs during this period, the participant will return to treatment and continue in the study (the PelliTec pad will not be used). If the ulcer does not recur, the participant is considered healed for the trial but should attend study visits 4 (week 9, telephone visit) and 5 (week 12, clinic visit).

Participants will be asked to complete the study questionnaires (EQ-5D-5L, CWIS, SF-36, CSRI) at Visits 3 and 5.

Weekly telephone contact will be maintained with each participant between study visits in order to check the use of the PelliTec pad.

One telephone interview will be conducted with each study participant to examine barriers and facilitators to the adoption of medical devices in the management of diabetic foot ulcers. This can be conducted at any point during the period of participant involvement in the study. Appointments will be booked when it is convenient to the participant. The specific themes that will be explored include understanding and impact of diabetic foot disease on daily activities and outlook, adaptations to daily routines as a result of diabetic foot disease, opinions on medical technology to assist daily living specific to diabetic foot ulcer healing/prevention, barriers and facilitators to the use of medical devices in the management of diabetic foot ulcers. Participants will be provided information sheets outlining the aim of the research and assuring participants that their responses would be anonymised to allow freedom to voice their opinions. They will also be informed that the interviews will be recorded to facilitate data analysis.

Participants will also be asked a short series of questions relating to their experience of wearing the pads - ease of use, comfort and durability/need for replacement of the pads and any concerns or suggested improvements relating to the form and function of the pads.

Example questions:
We would like to find out what you feel about wearing the PelliTec pads.
1. Did they stay in place where the podiatrist had fitted them?
2. If they came away/required replacement, was that an easy process? (Record details)
3. Were they comfortable to wear?
4. Do you feel they helped your ulcer to heal?
5. Would you be happy to continue using them/wear them again if need? (If not why not)
6. Do you have any suggestions for improving them?

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Feasibility assessed using:
1. The time needed to collect and analyse data (in days) measured at the end of the study
2. Screening logs of recruitment and retention strategies: the number of eligible participants, different methods of identifying/recruiting patients and willingness of clinicians to recruit participants, measured at the end of the study
3. Follow-up rates, response rates to questionnaires and adherence/compliance rates, measured at the end of the study

Secondary outcome measures
1. Performance (repeated measures difference test) and reliability of the PelliTec pads to reduce pressure in patients with diabetic foot disease reported as a reduction in pressures measurements before or after using the pads across a range of activities and repeated measurements measured using research-grade insoles at the end of the study
2. Barriers and facilitators to adoption of medical devices in the management of diabetic foot ulcers by undertaking an initial feasibility/usability evaluation of participants' experience of wearing the pads, assessed using qualitative data from patient feedback at the end of the study

Overall study start date
21/08/2020

Completion date
17/10/2023

Eligibility

Key inclusion criteria
1. Age >18 and less than 80 years old
2. Able and willing to give written informed consent
3. Diabetes (according to WHO criteria)
4. Distal symmetrical polyneuropathy confirmed by Michigan Neuropathy Screening Instrument (MNSI) score >3 with Loss of Protective Sensation (LOPS) as defined by any loss of sensation as per MNSI assessments.
5. Healed plantar diabetic foot ulcer
6. Doppler ultrasound positive for at least one pedal pulse in each foot
7. Able to understand and willing to comply with all the study requirements
8. Be available for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Active diabetic foot ulcers
2. Non-diabetic neuropathies
3. Active alcohol or substance abuse
4. Registered blind
5. Active/acute Charcot neuroarthropathy (chronic Charcot foot is not an exclusion criterion)

Date of first enrolment
18/09/2021

Date of final enrolment
17/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Tectores Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents are not available.

Intention to publish date
17/10/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No