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Investigating foot pressure measurements in people with and without diabetes

Submission date
01/02/2021

Recruitment status
No longer recruiting

Registration date
26/04/2021

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes is a common chronic medical condition which is associated with significant illness and death. The prevalence of diabetes is increasing and by 2025, it is estimated that around 5 million people in the UK will have a diagnosis of diabetes.
The 2016 Scottish Diabetes Survey reported that 5.4% of the population was recorded as having a diagnosis of diabetes. 88.3% of these people had Type 2 diabetes and 10.6% had Type 1. The NHS Highland health board had 17,100 people on the diabetes register at the end of 2016. The crude prevalence of diabetes in this region has increased from 4.9% to 5.2% in 2 years.
There are many complications associated with diabetes, broadly categorised as large vessel arterial disease, including myocardial infarction (heart attack), stroke and peripheral vascular disease and microangiopathy, with kidney disease and retinopathy (eye disease) being examples. People with diabetes are at increased risk of foot complications due to peripheral neuropathy and/or peripheral arterial disease. 5.7% of people with Type 1 diabetes and 3.9% of those with Type 2 in NHS Highland have a record of having had a foot ulcer.
Management of foot problems related to diabetes presents a significant financial cost to the NHS through primary and community care, outpatient costs, inpatient bed occupancy and prolonged hospital stays. It has been estimated that £650 million is spent by the NHS on foot ulcers and amputations per year.
In an effort to detect problems early and prevent foot ulceration, foot care screening programmes for people with diabetes are common practice. It is recommended that people are screened at diagnosis and annually thereafter by examining for neuropathy using a 10 g monofilament, peripheral pulses and observing for ulceration, callus or deformity. A person is then assigned a low, moderate, high or active risk category allowing referral of appropriate people for multidisciplinary foot care or protection. Although recommendations around foot screening exist, there is considerable variation in practice. Systematic reviews have shown problems with monofilament testing, reporting limited sensitivity due to variability in the number of foot sites tested and the location of these test sites.
Elevated plantar pressure measurements while walking (the distribution of force over the sole of the foot) have been increasingly recognised as a risk factor for foot ulceration. A study in the 1960s first showed that foot ulcers in leprosy tended to occur in areas of highest plantar pressure. Since then, with emerging technologies, studies have shown that dynamic plantar pressures are generally higher at the ulcer or previous ulcer location but a pressure threshold

that predicts foot ulceration has not yet been identified.
This study aims to explore whether a device used to measure plantar pressures could act as a more accurate, standardised screening method for foot complications in diabetes. Potentially, the plantar pressure measurements could then be used in the production of individualised offloading insoles or footwear.
The device, Footscan, is a platform with sensors designed to be placed on the floor to provide static or dynamic plantar pressure data as the person stands on or walks across the plate. A study on healthy people showed the Footscan platform has shown good repeatability and it is therefore possible to use it in the assessment of plantar pressure distribution. The device produces pressure measurements which can be viewed on a laptop and can link up with the existing NHS diabetes database. So far, the device has been used by professionals in the fields of sports and biomechanics. In order to identify whether there is a role in foot screening in diabetes, the researchers want to test the plantar pressures of healthy people, people with diabetes and those with known diabetic foot complications to first of all identify normal values and then the values which would indicate those with feet at risk of ulceration.

Who can participate?
1. Patients aged 18 to 85 with any form of diabetes attending the diabetes clinics at Raigmore Hospital in Inverness
2. A group of age, gender and BMI matched non-diabetic patients from other medical outpatient clinics
3. A further group of healthy volunteers from the Centre for Health Sciences

What does the study involve?
Participants will be asked to give informed written consent for participation in the study. The Footscan platform will be placed on the floor. The participant will stand on the plate without shoes or socks to record static pressure measurement. They will then walk across the plate three times to obtain three recordings of each foot. The data is downloaded at the time of recording. The plate will be cleaned with hard surface wipes in between each participant. Participants will be considered to be in the study from the time of giving informed consent until they have attended the clinic for plantar pressure measurements. Participation is expected to be about 30 minutes at the clinic.

What are the possible benefits and risks of participating?
This study will be low risk as it only involves participants with good mobility walking short distances. There is no immediate benefit to individuals participating in this study but they will contribute to research on using plantar pressures in diabetic foot screening.

Where is the study run from?
University of Highlands and Islands (UK)

When is the study starting and how long is it expected to run for?
January 2019 to June 2020

Who is funding the study?
NHS Diabetes Research Endowment Fund (UK)

Who is the main contact?
Prof. Sandra MacRury
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
260754

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 260754

Study information

Scientific Title
Investigating plantar pressure measurements and their potential role in a local diabetes foot screening pathway

Study objectives
The hypothesis is that plantar pressures can be reliably measured with the Footscan platform.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2019, West of Scotland Research Ethics Committee (Clinical Research and Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SJ, UK; +44 (0)141 232 1808; WoSREC5@ggc.scot.nhs.uk), REC ref: 19/WS/0059

Study design
Feasibility/pilot study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
See additional files

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

Interventions
The Footscan platform will be placed on the floor. The participant will stand on the plate without shoes or socks to record static pressure measurement. They will then walk across the plate six times to obtain three recordings of each foot or three times if on a 1 m platform. The data is downloaded by USB at the time of recording. The plate will be cleaned with hard surface wipes in between each participant.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Footscan platform

Primary outcome measure
Plantar pressures measured by the participant standing still on and then walking across the Footscan platform, measured at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
18/01/2019

Completion date
17/06/2020

Eligibility

Key inclusion criteria
1. Adult men and women over 18 years of age
2. Any form of diabetes
3. Attends Raigmore diabetes or retinal screening clinic
4. Able to walk unaided
5. Able to understand the patient information leaflet, able to consent and be consented

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
55

Key exclusion criteria
1. Under 18 years
2. Pregnant women
3. Unable to walk unaided
4. Lower limb amputees
5. Previous or current foot injuries, operations
6. Unable to consent or not able to understand the participant information leaflet

Date of first enrolment
01/04/2019

Date of final enrolment
01/04/2020

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
NHS Highland
Raigmore Hospital
Old Perth Road
Inverness
United Kingdom
IV2 3UJ

Sponsor information

Organisation
University of the Highlands and Islands

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Sponsor type
University/education

Website
http://www.uhi.ac.uk/en

ROR
https://ror.org/02s08xt61

Organisation
NHS Highland

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R&D Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/010ypq317

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Diabetes Research Endowment Fund

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
17/06/2021

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?
Participant information sheet			26/04/2021	No	Yes

Participant information sheet	version V1.6	20/06/2019	26/04/2021	No	Yes
Protocol file			26/04/2021	No	No
HRA research summary			26/07/2023	No	No