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An evaluation of different devices to detect diabetic neuropathy in feet of diabetic patients

Submission date
14/07/2023

Recruitment status
No longer recruiting

Registration date
24/08/2023

Overall study status
Completed

Last Edited
13/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nerve damage and loss of protective sensation (LOPS) is a complication of diabetes. This diabetic neuropathy (DN) can subsequently lead to further complications such as diabetic foot ulcers and even amputation of toes and lower limbs. It is therefore essential to monitor for the development of DN in diabetic patients. In standard clinical practice DN is checked for using a monofilament, a piece of nylon on a stick that is pushed onto the patient's foot; LOPS is the sign of DN having developed. Monofilament testing checks for damage to large nerve fibres. There is however evidence that small nerve fibres are damaged before the large nerves are affected. Using a practical, reliable, and simple tool to check for small nerve damage in a clinic setting may aid in detecting LOPS/DN earlier and optimising patient management. Medipin is a hygienic single-use device designed to check for small nerve fibre damage in feet. The main objective of this study is to determine how many patients have LOPS/DN when tested with the monofilament and Medipin device respectively and to what degree there is an overlap between the two tests. For this purpose a total of 139 patients will be assessed at a single clinic visit.

Who can participate?
Adult patients aged 18 years or older with type 2 diabetes.

What does the study involve?
A single visit, at which the participant is assessed with the monofilament and Medipin devices.

What are the possible benefits and risks of participating?
The possible benefit for participants and patients in the future is that Medipin testing may identify DN that monofilament testing does not. There are no major personal safety risks anticipated regarding the tests. Both the Medipin device and monofilament press or touch the skin for around 1 second at a time, but do not pierce or damage the skin.

Where is the study run from?
North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2023 to August 2024

Who is funding the study?
Medipin Limited (UK)

Who is the main contact?
Dr Leon Jonker, Leon.jonker@ncic.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
325532

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55937, IRAS 325532

Study information

Scientific Title
Comparison of devices for the detection of diabetic neuropathy; an evaluative diagnostic study. (short title: ‘MANDARIN’ , Medipin Assessment for Neuropathy in Diabetes, A Real-world INvestigation)

Acronym
MANDARIN

Study objectives
The main objective of this study is to determine how many patients have diabetic neuropathy when tested, with the monofilament and Medipin device respectively, and to what degree there is an overlap between the two tests.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/04/2023, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8379; coventryandwarwick.rec@hra.nhs.uk), ref: 23/WM/0095

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Diabetic neuropathy

Interventions
For this study, GP records will be screened to identify patients who have type II diabetes , and who meet the other inclusion criteria. Eligible patients will be invited to complete a postal survey. For those patients who respond positively with a completed reply slip expressing their interest, a researcher will then arrange a single study visit. During this visit, the study will be explained once more and patients can ask any questions they may have. Then written informed consent is obtained.
Once done, the patient will have three different diabetic neuropathy screening tests (2x monofilament and 1x Medipin), plus they complete two questionnaires (one quality of life, one neuropathy screening). At the end, patients will be informed of the results and they will also receive an info leaflet on foot (self) care for diabetic patients. Their GP will also be notified of the results. There is no follow-up required for the study itself.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medipin

Primary outcome measure
This study has only one study visit. At this visit, three primary outcome measures – all intended to screen for presence of diabetic neuropathy in the feet:
1. A 10g Monofilament device test will be conducted on the five plantar locations on both left and right foot. Presence of sensation will give 1 point each time; a score of 8 or lower indicates the presence of diabetic neuropathy.
2. A 10g Monofilament device test will be conducted four times on on dorsal side of hallux, proximal to toenail, on both left and right foot. Presence of sensation will give 1 point each time; a score of 3 or lower indicates the presence of diabetic neuropathy.
3. A Medipin device test will be conducted, one application on dorsal side of hallux, proximal to toenail, on both left and right foot. . Presence of sensation will give 1 point each time; a score of 1 or 0 indicates the presence of diabetic neuropathy

Secondary outcome measures
Measured at a single time point:
1. Age, years of diabetes, smoking status, blood pressure medication and diabetes medication, presence of any foot malformations measured using patient records
2. General quality of life score (EQ-5Q-DL)
3. Michigan Neuropathy Screening Instrument (MNSI) symptom questionnaire score

Overall study start date
25/04/2023

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Adult patients aged >=18 years
2. Patients with type II diabetes mellitus

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 139; UK Sample Size: 139

Total final enrolment
389

Key exclusion criteria
1. Aged <18 years
2. Any reasons for the patient being unable to follow the protocol, including lack of mental capacity to consent to taking part in the study (examples include dementia, severe learning disability).
3. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives (examples include receiving palliative care, active cancer treatment, patient immobile)
4. Amputation of a lower limb
5. Confirmed and ongoing wound/ulcer located on the foot

Date of first enrolment
01/05/2023

Date of final enrolment
20/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

Sponsor details
Pillars Building
Cumberland Infirmary
Infirmary Street
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Sponsor type
Hospital/treatment centre

Website
https://www.ncic.nhs.uk/

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Medipin Limited

Results and Publications

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

Intention to publish date
19/10/2024

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 1.1	20/04/2023	14/07/2023	No	Yes
Protocol file	version 1.1	20/04/2023	14/07/2023	No	No
HRA research summary			20/09/2023	No	No
Results article		19/10/2024	13/12/2024	Yes	No