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ODIN study, a long-term study to assess the presence and progress of diabetic neuropathy (impaired or lack of sensation in feet) using the Medipin pin-prick and monofilament devices

Submission date
06/11/2024

Recruitment status
Recruiting

Registration date
07/11/2024

Overall study status
Ongoing

Last Edited
07/11/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Diabetic neuropathy (DN) is a complication of diabetes that causes nerve damage, leading to a loss of protective sensation (LOPS) and potentially resulting in foot ulcers. Current guidelines recommend yearly screening for DN, but the methods and reasons for this are not well-defined, leading to varied testing practices. Different devices test different types of nerves, with the NHS mainly using a monofilament for large nerve fibres. However, small nerve fibres may be damaged earlier. This study, called the ODIN trial, aims to use both the Medipin (for small fibres) and monofilament (for large fibres) to track DN development and progression in diabetes patients.

Who can participate?
The study will include at least 214 patients who do not have neuropathy at the start of the study.

What does the study involve?
Participants will be tested with both the Medipin and monofilament devices to check their nerve function. They will be followed up over three years to see if their nerve sensation changes, from normal to reduced or absent sensation.

What are the possible benefits and risks of participating?
The study checks for diabetic neuropathy over a period of three years and also compares the Medipin test to normal NHS practice (testing with monofilament). This will therefore give patients an overview of how the sensation in their feet may change over time. It is possible the Medipin test may detect diabetic neuropathy where monofilament testing has not. Some participants may also be tested for the first time with the monofilament device, if they have not had this done before by their regular care team. By taking part, patients may possibly get support and treatment for diabetic neuropathy when otherwise they would not have. However, patients' GP and/or diabetes care team will continue to manage their diabetes, whether they take part in this study or not. Patients cannot claim payments, reimbursement of expenses or

any other benefits or incentives for taking part in this research (we will try and see patients close to their home to minimise any inconvenience).
There are no major personal safety risks anticipated regarding taking part in this study. The Medipin device and monofilament press or touch the skin of the big toe for around 1 second at a time. This may cause slight discomfort, but is actually essential to the test. The tests are checking if nerves sense the pressure of the monofilament, or the pinprick of the Medipin. There should be no lasting discomfort, pain, or skin damage. The monofilament will be sanitised in-between patients, as per standard practice. The Medipin is single-use and will be thrown away after being used on one patient.
If patients decide to take part in the study, and the NHS Trust, GP, or the research team learns of important new information that might affect their willingness to remain in the study, they will tell participants as soon as possible. Appropriate precautions are in place to ensure medical and personal information is kept safe.

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?
May 2024 to August 2028

Who is funding the study?
Medipin Limited (UK)

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

Contact information

Type(s)
Scientific

Contact name
Dr Leon Jonker

ORCID ID
http://orcid.org/0000-0001-5867-4663

Contact details
North Cumbria Integrated Care NHS FT, Penrith Hospital, New Bridge Lane
Penrith
United Kingdom
CA11 8HX
+44 1228 602173
Leon.jonker@ncic.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
342532

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 65006

Study information

Scientific Title
ODIN (Observation of DIabetic Neuropathy) study: A prospective cohort study screening for presence and progress of diabetic neuropathy in type II diabetes mellitus patients, using MEDIPIN pinprick and monofilament devices

Acronym
ODIN

Study objectives
In this ODIN trial the aim is to utilise both the Medipin and monofilament devices to describe the development and potential progression of DN in diabetes patients. The main objective is to see how many patients' status may go from 'no neuropathy' (sharp sensation with Medipin) to 'reduced sensation' (dull sensation), and from 'reduced sensation to no sensation' (complete absence of sensation).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/10/2024, Yorkshire and the Humber – South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048184; southyorks.rec@hra.nhs.uk), ref: 24/YH/0233

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

See outputs table

Health condition(s) or problem(s) studied
Diabetic neuropathy in type II diabetes mellitus patients

Interventions
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 (1x 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. For this study patients are follow up for three years (36 months). They will have a follow-up appointment at month 18 and month 36.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
1. Patients' sensation to Medipin pin-prick application (both ternary and visual analogue scale) will be measured at baseline (0 months), and at 18months and 36months follow-up
2. Patients' sensation to 10g monofilament application (ternary scale) will be measured at baseline (0 months), and at 18months and 36months follow-up

Secondary outcome measures
1. Patients' quality of life will be measured using validated EQ-5D-5L scale, done at at baseline (0 months), and at 18months and 36months follow-up
2. Patients' neuropathy related symptoms will be measured using validated Michigan Neuropathy Screening Instrument symptom questionnaire , done at at baseline (0 months), and at 18months and 36months follow-up
3. Patients' blood glucose control will be measured using HbA1c test (if results obtained as part of standard care) , done at at baseline (0 months), and at 18months and 36months follow-up
4. Patients' blood pressure will be measured using standard blood pressure measurement device (if results obtained as part of standard care) , done at at baseline (0 months), and at 18months and 36months follow-up

Overall study start date
01/05/2024

Completion date
31/08/2028

Eligibility

Key inclusion criteria
1. Adult patients aged >=18 years
2. Patients with type II diabetes mellitus (diagnosed in accordance with NICE guidelines, Oct 2023)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Aged < 18 years
2. Confirmed complete diabetic neuropathy (patients can be consented if this is not known beforehand, but will then not be included in diabetic neuropathy progression analysis)
3. 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).
3.1. 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, medical condition that contraindicates giving routine blood samples)
4. Amputation of hallux, foot, or complete lower limb (at baseline)
5. Confirmed and ongoing wound / ulcer located on the foot (at baseline). This may impede ability to conduct the DN tests (i.e., wound and dressing/bandage covering the hallux [big toe])

Date of first enrolment
01/12/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

Sponsor details
Pillars Building, Cumberland Infirmary, Infirmary Street
CarlIsle
England
United Kingdom
CA2 7HY
+44 1228608926
research@ncic.nhs.uk

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 peer-reviewed journal

Intention to publish date
01/11/2028

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 1.0	15/10/2024	06/11/2024	No	Yes
Protocol file	version 1.0	15/10/2024	06/11/2024	No	No