North Cumbria Integrated Care NHS Foundation Trust

[study logo]

Patient Information Sheet

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

- We would like to invite you to participate in a research study. Before you decide, you need to understand why this study is being done and what it will involve for you.
- Please take time to read the following information carefully.
- Talk to others about the study if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this information sheet.

Who is carrying out the study and why?

The study is led by Dr Stacey Fisher, a GP with a special interest in research. She works across a number of GP practices for North Cumbria Integrated Care NHS Foundation Trust, including yours, and is organizing the study. The study is run in collaboration with Dr Leon Jonker from the Research Department at North Cumbria Integrated Care NHS Foundation Trust, and local NHS research support staff.

People with diabetes are at risk of developing diabetic neuropathy. This is where diabetes causes damage to the nerves over time. One of the biggest dangers with diabetic neuropathy is loss of feeling/sensation in the feet. People may then get a small injury to their foot (like a blister, or stepping on something sharp) but not notice it. If untreated, these minor injuries could develop into ulcers (wounds) and may become infected. To reduce this risk, it is important people with diabetes have regular checks to monitor the sensation in their feet.

This study is looking at how many diabetic patients have (signs of) diabetic neuropathy and how this may progress over a longer period. This is done by testing patients three times over

the course of three years. We are using two medical devices to screen for diabetic neuropathy: the Medipin device, which is like a pin-prick that does not damage the skin, and also the standard NHS monofilament test (more details about these tests below). Depending on the type of test, there could be differences in the type of nerve damage they are able to find and how quickly nerve damage is detected. The findings of this study could affect how, and how often, diabetic neuropathy tests are done in the future.

Why have I been invited?

You have been invited to participate in this research study because you have type 2 diabetes. This means you may be at risk of diabetic neuropathy.

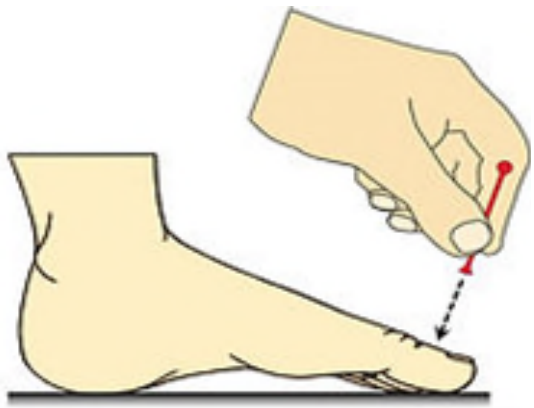
You may have had diabetic neuropathy checks before. You may have even been told you have (a degree of) diabetic neuropathy, but even in such instances you can still take part in this study.

What is being tested?

Medipin

Medipin uses a few small pinpricks to test for feeling in the feet. These will be on your arm, to get a comparison feeling ,and then on your big toe. It gets pressed against the skin but does not break the skin. The person doing the test will ask if you felt each pinprick or not. Medipin testing mainly tests for small nerve fibre function, which differs from monofilament testing (see next section). The device is single use, which means it gets thrown away after being used on one person. Medipin is approved to be used on patients and is used in some countries, but to date is not yet widely used in the UK's NHS.

Figure 1, The Medipin device, and a diagram of how it is used.



Monofilament

The NHS normally uses a so-called monofilament to test for diabetic neuropathy. A monofilament is a thin, wire-like piece of plastic. It gets pressed against the skin but does not break the skin. The person doing the test will press the monofilament against your skin of your large toe a few times, and ask you if you felt each press or not. Monofilament testing mainly tests for large nerve fibre function.

Figure 2, A monofilament test taking place.

Do I have to take part?

Your participation in the study is voluntary. You do not have to take part. It is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us if you would like more information or if anything is not clear. If you do decide to take part, you are free to leave the study at any time and do not have to give a reason why. If you leave the study, your care will not be affected. Your GP surgery will continue to monitor for diabetic neuropathy as per standard practice and clinical guidelines.

What will happen to me if I take part?

If you are interested in taking part in the study, please complete the reply slip and return it to us in the freepost envelope provided. We will then contact you to arrange your study visit. We can offer appointments at a number of locations across North Cumbria.

The study involves three visits, see Table 1. The visit will take approximately 10-15 minutes. The researcher can help you with completing questionnaires if you need assistance. Information on any relevant medical conditions you may have in addition to diabetes such as cardiovascular disease, and medication you may take for this, we will obtain from your medical records.

Table 1, What happens during the study visits

Baseline visit (month 0)	Complete informed consent form.
	Answer medical/general information questions (e.g. height, weight, medication, HbA1c level; can be taken from medical records if available). No new or additional measurements or tests.
Month 0, month 18 and month 36 visits	Fill in two questionnaires: • EQ-5D-5L (general quality of life questionnaire) • Michigan Neuropathy Screening Instrument (symptom questionnaire)
	Complete diabetic neuropathy tests on your feet: • Medipin test • Monofilament test
	Get diabetic neuropathy test results (results will be sent to your GP and uploaded to your GP medical records).

How does my GP get my results?

After the study visit, we will send a letter to your GP to let them know the results of your diabetic neuropathy check. If through the study, you find out you have diabetic neuropathy, your GP surgery can then decide how to progress with managing your care going forward. At the baseline ('month 0') study visit, all participants will be given an information leaflet about diabetic neuropathy and foot care tips. The main way to prevent complications with diabetic neuropathy is to look after and regularly check your own feet.

This study is separate to your normal regular diabetic neuropathy check. Your GP surgery may choose to use the results taken at your ODIN study visit for your annual check. Or they may want you to have a further check done by surgery staff when your check-up is due. It is also normal practice for us to put an entry on participants' medical record to say that you have taken part in a research study.

What are the possible benefits of taking part?

The study checks for diabetic neuropathy over a period of years and also compares the Medipin test to normal NHS practice (testing with monofilament). This will give you an overview of how the sensation in your 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. We will let you know what the test results show and we will also inform your GP of these outcomes.

By taking part, you may possibly get support and treatment for diabetic neuropathy when otherwise you would not have. Overall, your GP and/or diabetes care team will continue to manage you and your diabetes, whether you take part in this study or not.

You 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). With your consent, we can share a summary of the overall study findings with you when the study is complete.

What are the possible disadvantages and risks of taking part?

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 your 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 you do decide to take part in the ODIN study, and your NHS Trust, GP, or the research team learns of important new information that might affect your willingness to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

How will we use information about you?

We will need to use information from your medical records for this research project.

This information will include your name, sex, and age. Contact details (address and phone number) are used by the clinical team for appointments and your care. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a participant number instead, which is like a code number. We will keep all information about you safe and secure. Some of your information (anonymous study outcome data) will be sent to the funder of the research, Medipin Ltd. They must follow our rules about keeping your information safe.

We will send your GP a letter to inform your GP practice of the results of your diabetic neuropathy tests done for the ODIN study. As per normal practice, we will put an entry on your medical record to say you took part in a study.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. If you do then we will keep any information and study data we hold about you. However, we will not collect any new information.

Will my participation in the study be kept confidential?

Dr Fisher, a GP in your GP practice and at the Research Department of North Cumbria Integrated Care, has screened your details to ensure you are eligible to take part in the study. These details will not be shared with anyone else in the research team. All information that you give us will be kept strictly confidential. You will be asked to give your name and contact details because we wish to match this with your medical information.

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act and General Data Protection Regulation for health and care research. Your data collected during your participation in the ODIN study will be entered into a password-protected database and analysed – using only NHS computers and servers. For the data analyses, your study data will not be identified by your name – only by participant number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor's clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor's auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to the study files, but your medical records will not be accessed.

We will need to use information from you and from your GP medical records for this research project. This information will include your name. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What if something goes wrong?

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below). The study is covered by NHS insurance in relation to the design, management and conduct of the research, but not for no fault compensation.

What will happen if I don't want to carry on with the study?

Your participation in the study is voluntary. You can choose not to take part. You can leave the study at any time and do not have to give a reason why. If you leave after signing the study consent form, you will not be able to re-join the study. Any data collected up to the point where you leave will be kept for analysis as part of the study, but no new information will be collected. If you leave the study, your care will not be affected. Your GP surgery will continue to monitor for diabetic neuropathy as per standard practice and clinical guidelines.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At www.hra.nhs.uk/information-about-patients/
- By reading our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team, our contact details are further down this leaflet at 'Contact for further information'
- Within the sponsor NHS Trust for this study via the Data Protection Officer pals@ncic.nhs.uk

Who is organising and funding the study?

North Cumbria Integrated Care NHS Foundation Trust is the sponsor for the study, and Medipin Ltd will provide a research grant to the study team. The study has been reviewed and given a favourable opinion by the National Ethics Research Service ([name] Research Ethics Committee, REC ref: [number]), the Health Research Authority (reference 342532) and the NHS Trust (North Cumbria Integrated Care NHS Foundation Trust).

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

Contact for further information

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the ODIN research team:

- Name: Dr Stacey Fisher (Chief Investigator)
- Phone number: 01228 602173. If we miss your call, there is a confidential answer phone on this number.If you leave a message we will resond to you at the earliest opportunity.
- Email: Research@ncic.nhs.uk

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or PET@ncic.nhs.uk , or from websites such as the NHS Choices website, http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Independent advice can be obtained from the Patient Advice & Liaison Service (PALS)

Email: pals@ncic.nhs.uk , Telephone: 01228 814008

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