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A new intelligent eye imaging method to detect diabetic nerve damage early

Submission date	Recruitment status	[X] Prospectively registered
11/05/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/05/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/07/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetic peripheral neuropathy (DPN) is a common complication of diabetes. High blood sugar over time can damage the nerves, which are usually associated with changes in sensation or pain in the feet and hands. DPN is often only diagnosed once symptoms have become noticeable, and current tests look mainly at large nerve fibres or require invasive procedures such as skin biopsies. This means early nerve damage can be missed. There is a need for a simple, accurate and practical way to detect DPN earlier so treatment can start sooner and prevent further complications. The cornea, the clear curved surface at the front of the eye, contains small nerves. Research has shown that these nerves begin to change in early stages of DPN - even before symptoms appear - when using a technique called corneal confocal microscopy (CCM). However, CCM involves touching the eye with a camera for several minutes, which can be uncomfortable and is not suitable for everyone, especially for screening large numbers of people.

This study will test a new, contact-free eye imaging device called an optical coherence microscope (OCM), which can capture detailed images of corneal nerves without touching the eye. After an initial usability study with healthy volunteers, the study will invite participants into phase 1 and 2 clinical studies to assess how well the new device works. This device will also be integrated with artificial intelligence (AI), which can automatically analyse the images to detect signs of DPN. By combining quick, comfortable eye scanning with automated image analysis, this approach may offer a modern and widely accessible way to screen for DPN early.

Who can participate?

Adult patients aged 18 years or older with or without type 1 or 2 diabetes.

What does the study involve?

Participants will attend a study visit where several simple tests will be carried out to assess nerve and overall health. These include blood and urine tests, nerve conduction studies, cardiovascular autonomic reflex tests, and eye imaging scans (corneal confocal microscopy and optical coherence microscopy).

What are the possible benefits and risks of participating?
The knowledge gained from this study may affect the tests employed in the future to diagnose diabetic nerve damage. It may help to ensure that future patients are offered a more accurate diagnosis and receive the most effective treatment available. There are no recognised risks of any of the procedures proposed for this study. All tests are non-invasive except the routine blood tests taken at each visit. All tests will be carried out by trained clinical staff.

Where is the study run from?
The Clinical Sciences Centre at Aintree University Hospital in Liverpool, UK.

When is the study starting and how long is it expected to run for?
August 2026 to October 2027.

Who is funding the study?
The Engineering and Physical Sciences Research Council (EPSRC) has provided funding to the University of Liverpool for this research.

Who is the main contact?
Dr Kevin Shaji, Clinical Sciences Centre, Aintree University Hospital, Liverpool, kshaji2@liverpool.ac.uk.

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Integrated Research Application System (IRAS)
365672

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73069

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EP/X01441X/1

Study information

Scientific Title
Development of an innovative intelligent EYE imaging solution for SCREENing of diabetic peripheral neuropathy

Acronym
EYE-SCREEN-4-DPN

Study objectives
The study aims to assess the diagnostic performance of a novel optical coherence microscopy (OCM) device for identifying diabetic peripheral neuropathy, and to explore its suitability as a screening tool in clinical practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2026, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 26/NW/0060

Primary study design
Observational

Secondary study design
A prospective, multi-phase observational clinical study programme incorporating usability, longitudinal cohort, and cross-sectional case–control components.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus, polyneuropathies and other disorders of the peripheral nervous system

Interventions

(i) Usability study - 10 healthy volunteers
(ii) Phase 1 longitudinal clinical study - 50 participants, including patients with diabetes and age- and gender-matched healthy volunteers.
(iii) Phase 2 cross-sectional clinical study - 54 healthy volunteer participants and 116 patients with diabetes.

For the usability study, healthy volunteers will undergo imaging with the novel OCM device at the University of Liverpool. These volunteers will be recruited from the University of Liverpool, from health friends and family of patients at Aintree University Hospital of NHS University Hospitals of Liverpool Group.

For the phase 1 longitudinal study, 50 participants with diabetes and healthy age-gender matched volunteers will undergo routine diabetes-related blood and urine tests, standard-of-care clinical neuropathy tests, clinical questionnaires, autonomic neuropathy testing, corneal confocal microscope and the novel OCM. These participants will be followed up at 9-12 months to undergo the same tests from baseline.

For the phase 2 cross-sectional study, 54 healthy volunteers and 116 patients with diabetes will also undergo routine diabetes-related blood and urine tests, standard-of-care clinical neuropathy tests, clinical questionnaires, autonomic neuropathy testing, corneal confocal microscope and the novel OCM. For reproducibility, 10 participants among the 54 healthy volunteers and 20 from the 116 diabetic patients in the phase 2 cross-sectional study will be rescanned with the novel OCM only after 2-6 weeks.

Each visit in the clinical studies will include:

- Obtaining consent, reviewing medical history and concomitant medications
- Height, weight, resting heart rate and blood pressure
- Blood and urine tests
- Neurological examination with monofilament testing and vibration perception threshold
- Clinical questionnaires (Michigan Neuropathy Screening Instrument, Neuropathy Symptom Profile, painDETECT)
- Nerve conduction studies
- Autonomic neuropathy assessment (using VagusTM device)
- Corneal confocal microscopy (using HRT3 RCM confocal microscope, Heidelberg Engineering)
- Novel OCM device
- Participant experience of the assessment questionnaire

Intervention Type
Other

Primary outcome(s)
1. Diagnostic performance of the OCM device for detecting diabetic peripheral neuropathy, as defined by the Toronto criteria measured using various collected metrics, including sensitivity, specificity, precision (or positive predictive value), negative predictive value, F1 score and area under the curve, at one time point at baseline

Key secondary outcome(s)
1. Sensitivity, specificity, and area under the curve of OCM for diagnosing DPN measured using OCM imaging at one time point at baseline

2. Repeatability and reproducibility of the OCM in terms of corneal nerve parameters in a subset of 30 participants (10 healthy volunteers and 20 patients with diabetes) measured using OCM imaging at baseline and 2-6 weeks

3. Agreement and correlation between OCM and corneal confocal microscopy using corneal nerve metrics (corneal nerve fibre density, corneal nerve fibre length, corneal nerve branching density and inferior whorl length) measured using OCM imaging and corneal confocal microscopy (CCM) at one time point at baseline

4. Predictive ability of the OCM for DPN measured using OCM imaging at baseline and 9-12 months

5. Usability and feasibility of the OCM device in a clinical research setting measured using task performance metrics (completion rate, scan time, error rates), operator reproducibility, image quality measures (signal-to-noise ratio, artefact prevalence), system reliability, and human factors engineering methods, complemented by participant experience questionnaires, structured observations of use-related errors, and qualitative user feedback, at one time point at baseline

6. Image quality metrics of OCM imaging measured using data collected from OCM imaging at one time point at baseline

7. Performance of AI-based corneal nerve analysis adapted from CCM to OCM measured using OCM imaging CCM at one time point at baseline

Completion date
01/10/2027

Eligibility

Key inclusion criteria
Diabetes Cohort
1. Male or female aged > = 18 years old
2. Diagnosis of type 1 or type 2 diabetes mellitus documented in medical records or HbA1C > = 48mmol/mol at screening

Healthy Volunteer Cohort
1. Male or female aged > = 18 years old
2. No history or presence of any systemic disorders that may affect nerve fibres or cornea

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Unable to provide informed consent
2. Previous corneal transplantation or ocular trauma
3. Ocular surgery or laser eye treatment within 12 months before screening visit
4. Presence of non-diabetic neuropathies
5. Presence or history of aphakia
6. Presence or history of epilepsy or photosensitive seizures
7. Active corneal disease – not limited to dry eye disease, keratitis, keratoconus, corneal dystrophies, corneal ulcers, Fuchs' dystrophy, Sjogren's-associated dry eye disease
8. Active ocular disease – not limited to herpes zoster ophthalmicus, glaucoma, nystagmus
9. Any contraindication to nerve conduction studies – pacemaker, implanted electronic devices

Date of first enrolment
01/08/2026

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aintree University Hospital
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Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available in anonymised format upon request.

IPD sharing plan summary
Available on request