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Evaluating a new camera for diabetic eye disease screening in Afro-Caribbean and Asian populations without pupil dilation

Submission date 27/11/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/01/2025	**Overall study status** Ongoing	
Last Edited 12/02/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
People with diabetes can lose their sight because diabetes can damage their eyes. This damage can be detected early by taking pictures of the back of the eyes. Usually, eye drops are needed to get good quality pictures. Newer cameras, like the EIDON camera, might take high-quality images without needing eye drops. In Gloucestershire, 9 out of 10 people didn't need eye drops with these new cameras. This study aims to see if these new cameras work without eye drops in other areas of the country.

Who can participate?
People with diabetes who are scheduled for eye screening at Leyton Green in London can participate in this study.

What does the study involve?
Participants will receive a patient information leaflet two weeks before their eye screening appointment. On arrival, the study will be explained, and written consent will be taken. Participants will provide information on their sex, age, and ethnicity. The research imager will take one photograph of each eye with the EIDON camera without eye drops. Participants will then undergo the routine screening procedure, which includes using eye drops and taking two images of each eye. If the initial images from the EIDON camera are of poor quality, they will be repeated after using eye drops.

What are the possible benefits and risks of participating?
The main benefit is the potential to avoid the discomfort of eye drops, which can sting and blur vision, making it hard to drive or work afterwards. If the EIDON camera works well without eye drops, it could improve the screening experience for many people with diabetes. The risks are minimal, but there is a chance that the initial images might not be clear, requiring the use of eye drops as usual.

Where is the study run from?
Gloucestershire Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2024 to December 2026.

Who is funding the study?
Diabetes UK.

Who is the main contact?
Prof Peter Scanlon, p.scanlon@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336593

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
24/0006674, CPMS 59470

Study information

Scientific Title
Scanning CONfoCal Ophthalmoscopy foR DIAbetic eye screening (CONCORDIA 2) in Asian and Afro-Caribbean Groups

Acronym
CONCORDIA 2

Study objectives
The purpose of this study is to determine if the Eidon white light 60-degree field SCO camera is safe to use in staged mydriatic mode in a Diabetic Eye Screening Programme (DESP) for those people of Asian and Afro-Caribbean descent in a screening programme in London, England.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/09/2024, Black Country Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 24/WM/0182

Study design
Interventional non-randomized study

Primary study design
Interventional

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Diabetic eye screening

Interventions
We propose a clinical trial to determine the sensitivity and specificity of the EIDON scanning confocal ophthalmoscope (SCO) camera using a staged mydriatic approach in a screening cohort to detect any retinopathy in the central area covered by the standard two 45-degree photographs used in the English NHS DESP, and the proportion of ungradable images.

All participants will have images of their retinas taken with an EIDON SCO camera without mydriasis. The total duration of participation in the trial is around 30 minutes per participant, as they will have additional images taken with the new device before their pupils are dilated and then have their normal screening images taken for comparison. They will be asked to complete a short satisfaction questionnaire. If the images on the new device are not readable, they will be re-taken after the pupils are dilated. After this, their participation is finished as there is no follow-up for the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EIDON Scanning confocal ophthalmoscope

Primary outcome(s)
Sensitivity and specificity of the Eidon device for detecting any diabetic retinopathy within the area of the two 45-degree field mydriatic images against a reference standard of two-field digital photography at a single timepoint at the routine screening appointment

Key secondary outcome(s))
The following secondary outcome measures are assessed at a single timepoint at the routine screening appointment:
1. Sensitivity and specificity of the device for detecting referable DR within the area of the two 45-degree field mydriatic digital images against a reference standard of two-field digital photography
2. Proportion of ungradable images measured using recorded data
3. Proportion of images that are gradable on the Eidon SCO device that are ungradable on the digital images measured using recorded data
4. Inter-and intra-grader agreement for detecting any DR measured using recorded data
5. Microaneurysm counts within 1DD of the central fovea, the macular area, and the area of the two 45-degree fields (SCO images and digital images)
6. The screener and participant's perspectives of the device measured using a graphical feedback question
7. Lesions detected outside the standard fields and whether this alters the NSC grade or referral outcome measured using recorded data

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. People with diabetes giving informed consent
2. Those that meet the inclusion criteria for the National DESPs who are people with diabetes over the age of 12 years except for those under 16 years attending their first screening appointment
3. Asian or Afro-Caribbean descent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
99 years

Sex

All

Key exclusion criteria
1. People in whom it is not possible to take retinal images (it is normally not possible to obtain adequate images to grade in a small number of people in a screening population due to opacities in the media e.g. cataract, corneal scarring etc. or due to disability making it impossible for the individual to place their chin on a chin rest and other forms of screening are required in these individuals).
2. People or parents unable or unwilling to give informed consent.
3. Those with eye disease that might affect interpretation of DR levels e.g. branch or central retinal vein occlusion.
4. Children under 16 years of age attending for their first retinal screening appointment, which will automatically exclude children 12 years old and under as this is when they are first invited

Date of first enrolment
01/02/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leyton Green Clinic
Leyton Green Road
Leyton
London
United Kingdom
E10 6BL

Sponsor information

Organisation
Gloucestershire Hospitals NHS Foundation Trust

ROR
https://ror.org/04mw34986

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK

Alternative Name(s)
DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request: p.scanlon@nhs.net

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes