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Assessing whether the images taken of the back of the eye using new devices called scanning confocal ophthalmoscopes are of suitable quality to be used in the diabetic eye screening programme for the diagnosis of diabetic eye disease

Submission date	Recruitment status	[ ] Prospectively registered
15/06/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/09/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/01/2024	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes affects 4.7 million people in the UK. A common complication is diabetic retinopathy (DR), where there is damage to the blood vessels in the eye. Screening for early detection of DR has contributed to reducing blindness due to diabetes in the UK. This is carried out each year by using photography of the back of the eye (the retina). In England and Wales, the pupils are dilated with eye drops and then two 45-degree photographs of each eye are taken which gives a combined photographic width of 60 degrees of retina.

Scanning confocal ophthalmoscopes (SCO) are cameras that use low-powered laser or LED light to scan across the retina without the need for a bright flash and the width of one photograph varies from 60 - 200 degrees. This means only one photo of each eye is needed and pupil dilation may not be required. This would be an advantage as pupil dilation takes time, can be uncomfortable, and blurs the vision for several hours, meaning most people need to be accompanied to screening appointments and can't drive afterwards. Better accuracy, shorter appointment times, and the elimination of eye drops could increase the number of people who attend eye screening and DR could be caught earlier which may reduce the risk of vision loss.

At present, it is unknown whether white light LED or laser light is better for detection of DR, or if a wider photo might pick up more pathology in the wider retina but may pick up less in the centre. Both might have an effect on referral to hospital eye clinics (HEC). This study will assess the accuracy of two new cameras when screening for any eye disease caused by diabetes to find out whether the new cameras are as good as the current system or offer improved detection.

Who can participate?
Patients with diabetes who meet the inclusion criteria for the National Diabetes Eye Screening Programme in the UK. These will be people with diabetes over the age of 12 years (except for those under 16 years attending their first screening appointment)

What does the study involve?
The researchers will use some data from another similar study where people attending their routine screening appointment were asked to have one extra photograph taken of each eye by each of the cameras before pupil dilation, followed by the normal screening procedure. If the image quality was poor they were asked to have a further photograph taken of each eye with the new cameras after their pupils were dilated. The researchers will collect additional images in the same way from a second group of patients who will have one extra image of each eye taken with a third camera. The information from the images will be combined to see which camera provides the best photographs for screening. Participants will be asked for their opinion on having their eyes examined on the existing and new cameras. This is a single appointment visit and no study follow up is required.

What are the possible benefits and risks of participating?
There are no anticipated risks of taking part in the study or any direct benefits to the participants. The benefits may be in the future if these devices are considered an improvement and are adopted into the National Screening Programme. The extra images will add an extra 30 minutes to a participant's appointment time but this was felt to be acceptable providing clear information is given and extra parking costs are reimbursed.

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

When will the study take place?
October 2020 to May 2023

Who is funding the study?
1. Innovate UK
2. Optos UK
3. Centre Vue (UK)
4. RetinaScan Ltd (UK)

Who is the main contact?
Prof. Peter Scanlon
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297725

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
9j 07/04/2021, IRAS 297725, CPMS 49321

Study information

Scientific Title
Scanning CONfocal Ophthalmoscopy foR DIAbetic eye screening

Acronym
CONCORDIA 1

Study objectives
To assess the sensitivity and specificity of retinal images taken using the Optos California and the Zeiss Clarus or the CentreVue Eidon scanning ophthalmoscopes with staged mydriasis

compared with standard two 45-degree photographs taken following mydriasis as currently used in the English National Diabetic Eye Screening Programme. Also, a health economic study to determine their cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/08/2021, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8019, +44 (0)207 104 8370, +44 (0)207 104 8071; cornwallandplymouth.rec@hra.nhs.uk), REC ref: 21/SW/0064

Study design
Single-centre diagnostic accuracy study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format

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

Interventions
The interventions are three different SCO devices that are compared with the standard digital images taken in the English National Screening programme.

Work package 1 is using data from two devices (Optos and Clarus) collected in another study (AIDED). The device order was randomised but not concealed for the operator as this isn't possible. Work package 2 will collect additional data using a third SCO device (Eidon). The duration of participation in the trial is around 30 mins per participant, as they will have additional images taken with the new devices 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 and the EuroQoL EQ5D-5L which is part of the data collection for the health economics element in work package 3. 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)
Zeiss Clarus with an 88-degree (external) field, Optos California with a 135-degree (external) field, CentreVue Eidon with a 60-degree field (UK supplier Mainline)

Primary outcome measure
Sensitivity and specificity of the Optos, Clarus and Eidon devices 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. All the data are collected at a single timepoint which is at the routine screening appointment.

Secondary outcome measures
All the data are collected at a single timepoint which is at the routine screening appointment:
1. Sensitivity and specificity of the SCO devices 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
3. Proportion of images that are gradable on the Eidon SCO device that are ungradable on the digital images
4. Inter-and intra-grader agreement for detecting any DR
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. Screener and participant's perspectives of the device assessed using a graphical feedback question
7. Lesions detected outside the standard fields by the Optos, Clarus and Eidon devices and whether this alters the NSC grade or referral outcome
8. Health-related quality of life measured using the EuroQol EQ-5D-5L to support the cost-effectiveness study (for work package 3)
9. Time taken to capture and grade images by device type recorded automatically via the software used in the screening department (for the health economic analysis in work package 3)

Overall study start date
07/10/2020

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. People with diabetes giving informed consent
2. Those that meet the inclusion criteria for the national diabetic eye screening programme (DESPs), who are people with diabetes over the age of 12 years except for those under 16 years attending their first screening appointment

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
867

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
01/07/2021

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Gloucestershire Royal Hospital
Gloucestershire Hospitals NHS Foundation Trust
The Orchard Centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/04mw34986

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name

Optos Ltd

Funder Name
Centre Vue

Funder Name
RetinaScan Ltd

Results and Publications

Publication and dissemination plan
The researchers will link into wider networks of people with diabetes, locally and nationally through Diabetes UK, Facebook groups, and other social media to disseminate the findings to the public and through peer-reviewed journals and conferences to the clinical community.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator Prof. Peter Scanlon (p.scanlon@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No