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Visual function in retinal degeneration

Submission date 17/08/2022	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☒ Protocol
Registration date 18/08/2022	**Overall study status** Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 16/06/2025	**Condition category** Eye Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The study uses some of the most up-to-date techniques to assess different aspects of vision in patients with retinal degeneration. Visual function tests allow measurement of the level of vision such as reading letters on a letter chart. Whereas visual field assessments involve measuring the size of a seen area or the eyes' sensitivity to a particular light level in an area. Ocular imaging involves using a number of devices to capture images of the retina, the light-sensitive part of the eye. This study will enable us to use the latest tests and assessment methods to determine the suitability and usefulness of these visual assessments in patients with inherited retinal disease.

Who can participate?

Health volunteers can participate as well as patients with a genetically confirmed inherited retinal disease.

What does the study involve?

The study involves completing a series of letter chart tests and central visual field tests. Tests are completed on each eye and then repeated on the right eye. For patient participants, the study involves the completion of questionnaires about their vision. Some patient participants will also be invited to take part in a recorded interview to understand how they found the different tests.

What are the possible benefits and risks of participating?

There is no direct participant benefit from taking part in the research aside from contributing to knowledge to improve future patient care.

The extra tests may be slightly tiring, participants will be able to take breaks when needed.

There is a risk that an unknown eye condition in control participants could be detected, if this occurs the participant will be advised to go to their optometrist for an eye test.

Where is the study run from?

Oxford Eye Hospital, Oxford, England (UK)

When is the study starting and how long is it expected to run for?

May 2020 to January 2024

Who is funding the study?
This project is funded by the National Institute for Health and Care Research (NIHR) (UK) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR202821).

Who is the main contact?
Laura Taylor, trials@eye.ox.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
286579

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 286579, CPMS 47247, NIHR202821

Study information

Scientific Title
A cross-sectional study to assess the clinical utility of modern visual function assessments in patients with inherited retinal disease

Acronym
VFIRD

Study objectives
To investigate the clinical utility of degeneration targeting tests of visual function and compare them to the standard measures currently used in patients with retinitis pigmentosa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/01/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 207 104 8141; blackcountry.rec@hra.nhs.uk), ref 20/WM/0283

Study design
Single-centre prospective cross-sectional observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Visual function in patients with inherited retinal disease

Interventions
There will be two arms to the study. The first arm will include control participants. The second arm will include patient participants with confirmed inherited retinal disease. All participants will undergo the same visual field and visual acuity tests. Patient participants will also complete questionnaires. The assessments will take place during a single visit lasting no longer than 120 minutes with breaks included if required, this is in addition to the routine clinical care appointment which typically lasts around 120 minutes including waiting time.

Intervention Type
Other

Primary outcome(s)
VIsual function measured at a single time point:
1. Visual acuity
2. Low luminance visual acuity
3. Mesopic microperimetry

Key secondary outcome(s))
Visual function measures and visual field tests measured at a single time point:
1. Moorfields Acuity Chart Test
2. Scotopic Microperimetry
3. Low Luminance Questionnaire

4. Obtain qualitative data via semistructured interviews of patient participants in the day following completion of the study tests. The interviews will explore how the tests made the participants feel and whether any changes or improvements can be made to make the tests more acceptable and accessible.

Completion date
01/01/2024

Eligibility

Key inclusion criteria
Patient participants:
1. Participant is willing & able to give informed consent for participation in the study.
2. Male or female, aged 16 years or above, there is no upper age limit.
3. An inherited retinal degeneration diagnosis
4. A minimum of 6/60 standard VA in each eye.
5. Able to participate in visual function testing.

Control participants:
1. Participant is willing & able to give informed consent for participation in the study.
2. Male or female, aged 16 years or above, there is no upper age limit.
3. A minimum standard VA of 6/7.5 in each eye – this will only become apparent once the participant starts the study, if it is clear they do not meet this criterion, they will be excluded from the study and no further testing undertaken.
4. Able to participate in visual function testing.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
81

Key exclusion criteria
Patient participants:
1. Pre-existing amblyopia or squint would exclude that eye, but other eye still eligible
2. History of other eye problems except those relevant to the study, or glasses or contact lenses, if eye problem in just one eye, the other eye is still eligible
3. Been involved in an interventional research trial where they have received a treatment for their eye condition.

Control participants:
1. Pre-existing amblyopia or squint, fellow eye still eligible
2. History of eye problems, eye treatment or eye surgery other than glasses or contact lenses, if in one eye, fellow eye still eligible.

Date of first enrolment
13/08/2021

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Oxford Eye Hospital
Lower Ground 1
West Wing
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

A data management plan has been created. Results will be made available by the publicly available University of Oxford data repository upon completion of the study and publication of study results.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2025	16/06/2025	Yes	No
Protocol article		24/05/2023	25/05/2023	Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet	Control version 3.0	21/01/2022	17/08/2022	No	Yes
Participant information sheet	Patient version 4.0	11/04/2022	17/08/2022	No	Yes