ISRCTN88711666 https://doi.org/10.1186/ISRCTN88711666

Investigating methods of measuring visual field sensitivity in glaucoma

Submission date
20/04/2023

Recruitment status
Recruiting

Registration date
21/04/2023

Overall study status
Ongoing

Last Edited
05/06/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Glaucoma is characterised by a slow, irreversible loss of visual field. It is the world's leading cause of irreversible blindness, affecting about 500,000 people in England and Wales and 80 million people worldwide. With an ageing population, the prevalence of glaucoma is rising. Perimetry, the clinical method for identifying visual field loss, involves presenting stimuli (spots of light) on a screen and determining the dimmest that can be detected at multiple locations in the field. However, the current standard perimetry test was designed over 40 years ago, before the disease mechanisms in glaucoma were understood. There is a timely need to better understand how people with glaucoma detect perimetric stimuli, with 40 years of knowledge and understanding from basic science and clinical studies. The aim of this study is to better understand how patients with glaucoma respond to visual stimuli of different configurations. Specifically, the researchers will measure differences in the limits of vision and differences in variability between them.

Who can participate?
Patients over 40 years old with primary glaucoma or with no eye conditions. People who wear glasses or contact lenses for short-sightedness, long-sightedness or for reading will be eligible depending on their prescription.

What does the study involve?
Participants are invited to attend one of the research sites on one or more visits to undertake some measurements of their peripheral vision (visual field). Participants can choose to come to a research site in either Wales (Cardiff), Northern Ireland (Belfast or Coleraine), or England (London). Participants will undertake some standard clinical tests initially to confirm eligibility to participate. They will then undertake a series of visual field tests which will involve looking at a target at the centre of a screen and pressing a button when they see any spots appear in their peripheral vision. Only one eye (the eye that best meets the inclusion criteria) will be tested. Breaks will be given at regular intervals during testing and where requested.

What are the possible benefits and risks of participating?
There are no direct benefits for participants, except the knowledge that they are helping with research into ways of measuring the visual field in glaucoma. The visual tests are non-invasive

and carry no more risk than watching television. There are no known side effects associated with them. All of the eligibility screening tests are performed with commercially available clinical equipment and are routinely carried out in an optometrist's practice or hospital eye clinic and do not pose any risk to eye health. The eye pressure measurement will involve having a mild anaesthetic eye drop (as is standard in an optometrist's practice or hospital eye clinic), but this will wear off after about 20 minutes. Participants are advised not to rub their eye during this time. Sometimes, during the course of research, an abnormality of the eye may be discovered which the participant had previously been unaware of. In the event of any previously undiscovered abnormality being detected during the course of this study, participants will be referred to the appropriate healthcare professional, with their consent, in the same manner as they would be referred by a local optometrist.

Where is the study run from?
This study is being run by Cardiff University, along with Ulster University and UCL (UK)

When is the study starting and how long is it expected to run for?
December 2021 to October 2025

Who is funding the study?
The Medical Research Council (MRC) (UK)

Who is the main contact?
1. Dr Tony Redmond, RedmondT1@cardiff.ac.uk
2. Becky Vangasse, VangasseR@cardiff.ac.uk

Study website
https://www.cardiff.ac.uk/research/explore/research-units/research-and-evaluation-of-area-modulation-perimetry

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298826

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 298826, CPMS 52475

Study information

Scientific Title
Novel perimetry for identifying changes in visual field sensitivity in glaucoma

Acronym
REVAMP

Study objectives
Observational study: There is a timely need to better understand how people with glaucoma detect visual field test (perimetric) stimuli with 40 years of knowledge and understanding from basic science (physiological, psychophysical) and clinical studies. In this multi-disciplinary, multi-site project, we wish to better understand how people with glaucoma and normally-sighted individuals respond to visual stimuli and also gain an idea of how variable measurements are with each.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 13/04/2022, London – Surrey Research Ethics Committee (Nottingham Centre, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)2071048388, surrey.rec@hra.nhs.uk), ref: 22/PR/0241

Study design
Multicentre cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Other

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Investigating peripheral visual sensitivity in people with glaucoma and normally-sighted individuals

Interventions
1. Eligibility screening tests:
1.1. Questions about eye and general health history, family history, and current medications
1.2. Measurement of vision on a standard eye chart
1.3. Measurement of eye pressure, d) two visual field tests
1.4. Observation of the eye and screening for conditions that may affect vision
1.5. Measurement of eye length (non-invasive)
1.6. Retinal thickness scan with optical coherence tomography (OCT)

2. Measurement of visual sensitivity with psychophysics at multiple locations in the visual field. Investigations will be:
2.1. Differences in sensitivity between people with glaucoma and normally-sighted individuals
2.2. Variance in the sensitivity measures

Intervention Type
Not Specified

Primary outcome measure
The difference in visual sensitivity between patients and normally-sighted individuals is measured at months 11, 22, and 39

Secondary outcome measures

Variance of visual sensitivity in patients and normally-sighted individuals is measured at months 11, 22, and 39

Overall study start date
01/12/2021

Completion date
31/10/2025

Eligibility

Key inclusion criteria
Patients with glaucoma:
1. Diagnosis of Primary Open Angle Glaucoma (POAG) or Normal Tension Glaucoma (NTG) by the hospital eye service
2. Visual field defect consistent with glaucomatous optic nerve appearance.
3. Stable IOP <21 mmHg
4. Refractive error < ±6.00DS and <3.50DC
5. Visual acuity of 6/9 (+0.3 logMAR) or better in the test eye, in the absence of significant corneal or media opacities
6. Age over 40 years

Normally-sighted individuals:
1. No clinical diagnosis of glaucoma or other retinal disease
2. Full visual field
3. Healthy optic disc
4. No family history of glaucoma (first-degree)
5. Refractive error <±6.00DS and <3.50DC
6. Visual acuity of 6/9 (+0.3 logMAR) or better in the test eye, in the absence of significant corneal or media opacities
7. Age over 40 years

Participant type(s)
Mixed

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
157 patients with glaucoma; 230 normally-sighted individuals

Key exclusion criteria

1. Any systemic disease and/or medication which is likely to affect visual performance (e.g. diabetes, thyroid disease)
2. Any ocular disease and/or medication that may affect visual performance (apart from glaucoma)
3. Any previous ocular surgery which may degrade visual performance (e.g. corneal graft, photodynamic therapy)
4. Inability to steadily fixate during the test (e.g. individuals who have nystagmus or macular degeneration)

Date of first enrolment
01/08/2022

Date of final enrolment
15/10/2025

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Wales

Study participating centre
Cardiff University
Cardiff University
Maindy Road
Cathays
Cardiff
United Kingdom
CF24 4HQ

Study participating centre
Ulster University
Cromore Road
Coleraine
United Kingdom
BT52 1SA

Study participating centre

Cardiff and Vale University Health Board
University Hospital of Wales
Heath Park Way
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Northern Ireland Clinical Research Network
Royal Victoria Hospital
274 Grosvenor Rd
Belfast
United Kingdom
BT12 6BA

Study participating centre
NIHR Moorfields Biomedical Research Centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
United Kingdom
EC1V 2PD

Sponsor information

Organisation
Cardiff University

Sponsor details
Research Integrity, Governance and Ethics Team
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Sponsor type
University/education

Website
https://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal articles.

Intention to publish date
31/10/2026

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from the Principal Investigator (Dr Tony Redmond; RedmondT1@cardiff.ac.uk), or via the Cardiff University Research Portal, after protection of IP and publication of the study findings. Requests for access will be reviewed by a panel comprising: the PI, one co-applicant from each of the study sites, and independent input from the chair of the Steering Committee

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