

Study of technologies for the diagnosis of angle closure glaucoma

Submission date 25/01/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/08/2024	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

The ACE study is trying to find out whether people referred by an optician with possible angle closure could be safely diagnosed by healthcare professionals other than eye doctors. Patients will be helping us to determine whether other health professionals besides eye doctors could look after people who have been referred to the eye clinic with angle closure. If the research confirms that this is the case, this will relieve doctors' time in the NHS and doctors could then see patients with serious eye diseases who require treatment more promptly. In the long term, this would potentially help with waiting times in the NHS. If the study shows that having other health professionals see patients once they are stable is not as good as having doctors evaluating them, then this strategy will not be implemented in the NHS.

Who can participate?

Adults (≥ 18 years) referred from community optometry to hospital eye services with suspected angle closure

What does the study involve?

Some images will be obtained from the front of the patient's eyes and the patient will also be seen by an optometrist and an eye doctor at the clinic. Some information about participants will be noted in relation to age, gender, postcode, prescription glasses etc and patients will also be asked to complete a quality-of-life questionnaire.

What are the possible benefits and risks of participating?

Patients will be helping us to determine whether other health professionals besides eye doctors could look after people referred to the eye clinic with angle closure. If this is the case this will relieve doctors' time in the NHS and doctors could then see patients who need treatment more promptly. Participants may help with waiting times in the NHS. There are no risks associated with the study.

Where is the study run from?

Queens University Belfast (UK)

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

July 2022 to August 2024

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (UK)

Who is the main contact:

1. Ms Mary Guiney (Public), mary.guiney@nictu.hscni.net

2. Prof. Augusto Azuara Blanco, (Scientific) a.azuara-blanco@qub.ac.uk

Contact information

Type(s)

Principal Investigator

Contact name

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

315388

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

B22/08, CPMS 55578, IRAS 315388

Study information

Scientific Title

Study of technologies for the diagnosis of angle closure glaucoma (ACE)

Acronym

ACE

Study hypothesis

That the two non-contact tests being investigated for diagnosing angle closure glaucoma will be accurate and facilitate a safe and efficient pathway for patients with this condition compared with gonioscopy (reference standard) by an expert consultant ophthalmologist

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/12/2022, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0) 207 104 8171; cityandeast.rec@hra.nhs.uk), ref: 22/LO/0885

Study design

Prospective cross-sectional multi-centre diagnostic study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital, Optician

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Condition

Angle-closure glaucoma

Interventions

This is a diagnostic accuracy study. The tests will be used for triage. The study aims to propose a novel patient pathway. To evaluate the diagnostic performance of two non-contact diagnostic tests compared to gonioscopy (reference standard) by an expert consultant ophthalmologist. Anterior segment optical coherence tomography (AS-OCT) will be interpreted by optometrists and photographers/imaging technicians and ophthalmologists. Limbal anterior chamber depth (LACD), will be interpreted by optometrists.

There is one visit per patient at the hospital eye clinic services. Testing will be carried out face to face, on an individual basis per patient.

Intervention Type

Other

Primary outcome measure

Sensitivity and specificity of the new pathway to detect angle-closure glaucoma measured using standard formulas and pre-specified criteria for test positivity. All tests will be done at the same clinic visit.

Secondary outcome measures

The following outcome measures will be assessed and recorded in patient notes at the same clinic visit:

1. Positive/negative likelihood ratios for angle-closure glaucoma development measured using standard formulas
2. Concordance measured using standard formulas
3. Long-term health and cost outcomes measured using a Markov model run over an expected lifetime time horizon
4. Proportion of patients requiring subsequent clinical assessment by ophthalmologist measured using descriptive statistics
5. Proportion of patients unable to undergo tests and of tests of inadequate quality measured using descriptive statistics
6. Health-related quality of life measured using the EuroQol Health Questionnaire (EQ-5D-5L)

Overall study start date

01/07/2022

Overall study end date

31/12/2024

Eligibility

Participant inclusion criteria

Adults (≥ 18 years) referred from community optometry to hospital eye services with suspected angle closure glaucoma

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600

Total final enrolment

600

Participant exclusion criteria

Unable to provide informed consent

Recruitment start date

03/04/2023

Recruitment end date

30/07/2024

Locations**Countries of recruitment**

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

Belfast Health and Social Care Trust

Trust Headquarters

A Floor - Belfast City Hospital

Lisburn Road

Belfast

United Kingdom

BT9 7AB

Study participating centre

NHS Lothian

Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

Cardiff & Vale University Lhb

Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre

Moorefields Eye Hospital NHS Foundation Trust

Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
United Kingdom
EC1V 2PD

Study participating centre

Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus

Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre

Norfolk and Norwich University Hospital

Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre

Central Manchester University Hospitals NHS Foundation Trust

Trust Headquarters, Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

Sandwell and West Birmingham Hospitals NHS Trust

City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

Study participating centre

King's College Hospital NHS Foundation Trust

Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

Portsmouth Hospitals University National Health Service Trust

Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation

Queen's University Belfast

Sponsor details

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Sponsor type

University/education

Website

<http://www.qub.ac.uk/>

ROR

<https://ror.org/00hswnk62>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

It is anticipated that the study findings will be published in national and international peer review journals and these articles will be led by the CI. This will secure a searchable compendium of these publications and make the results readily accessible to the public and healthcare professionals. In addition, study findings may be presented at both national and international meetings and to appropriate patient groups.

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request following the publication of the primary and secondary outcomes. Formal requests for data should be made in writing to Prof. Augusto Azura-Blanco (Chief Investigator) via the Trial Manager, Mary Guiney (ACE@nctu.hscni.net). Requests will be reviewed on a case-by-case basis in collaboration with the Sponsor.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol article		04/10/2023	05/10/2023	Yes	No