ISRCTN15115867 https://doi.org/10.1186/ISRCTN15115867

Study of technologies for the diagnosis of angle closure glaucoma

Submission date
25/01/2023

Recruitment status
No longer recruiting

Registration date
10/03/2023

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Eye Diseases

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

Plain English summary of protocol

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 April 2025

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), Ace@nictu.hscni.net
2. Prof. Augusto Azura Blanco, (Scientific) a.azuara-blanco@qub.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Augusto Azuara-Blanco

ORCID ID
https://orcid.org/0000-0002-4805-9322

Contact details
Centre for Public Health
Institute of Clinical Science A
Queen's University Belfast
Grosvenor Road
Belfast
United Kingdom
BT12 6BA
+44 (0)28 9097 6350
a.azuara-blanco@qub.ac.uk

Type(s)
Public

Contact name
Mrs Mary Guiney

Contact details
Northern Ireland Clinical Trials Unit (NICTU)
7 Lennoxvale
Belfast
United Kingdom
BT9 5BY
+44 (0)28 9615 1447
ACE@nictu.hscni.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315388

Protocol serial number
B22/08, CPMS 55578

Study information

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

Acronym
ACE

Study objectives
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

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
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(s)
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.

Key secondary outcome(s))
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)

Completion date
09/04/2025

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

641

Key exclusion criteria
Unable to provide informed consent

Date of first enrolment
03/04/2023

Date of final enrolment
30/07/2024

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

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

Study participating centre
James Paget University Hospitals NHS Foundation Trust
Lowestoft Road
Gorleston
Great Yarmouth

United Kingdom
NR31 6LA

Study participating centre
Bedford Hospital NHS Trust
South Wing
Kempston Road
Bedford
United Kingdom
MK42 9DJ

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Central Middlesex Hospital NHS Trust
Acton Lane
Park Royal
London
United Kingdom
NW10 7NS

Study participating centre
Mid Essex Hospital
Broomfield Hospital
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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@nictu.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?
Protocol article		04/10/2023	05/10/2023	Yes	No
HRA research summary			26/07/2023	No	No