ISRCTN13728688 https://doi.org/10.1186/ISRCTN13728688

Treatment of retinal detachment in people who have not had cataract surgery and are not very short-sighted with either vitrectomy surgery alone or with vitrectomy and removal of the cataract at the same time

Submission date
11/04/2025

Recruitment status
Recruiting

Registration date
17/04/2025

Overall study status
Ongoing

Last Edited
01/04/2026

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims

The retina is the layer at the back of the eye that allows us to see. Sometimes, it can detach from the wall of the eye, causing a condition called rhegmatogenous retinal detachment (RRD), which leads to vision loss and requires surgery. The most common surgery for RRD is vitrectomy, but this can lead to complications like cataracts, which worsen over time and need to be removed with another surgery. Cataract surgery involves replacing the cloudy lens with a clear artificial one. Currently, it's unclear whether it's better to perform both surgeries at the same time or separately. The COMBAT study aims to find out which approach is best by comparing the outcomes of patients who have vitrectomy alone versus those who have both surgeries together.

Who can participate?

Adults aged 50 and older who have RRD but are not highly myopic (less than -6 diopters or an axial length of 26.5 mm or less) and have not had previous vitreoretinal surgery. Participants must be scheduled for a pars plana vitrectomy to repair their RRD.

What does the study involve?

Participants will be randomly assigned to one of two groups: one group will have vitrectomy first and, if needed, cataract surgery later; the other group will have both surgeries at the same time. The study will compare their vision, the number of successful retina reattachments, patient satisfaction, complications, and costs.

What are the possible benefits and risks of participating?

The possible benefits include improved vision and a better understanding of the best surgical approach for RRD. However, there are risks associated with any surgery, including complications from vitrectomy and cataract surgery.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
November 2024 to October 2028.

Who is funding the study?
Queen's University Belfast (UK)

Who is the main contact?
Colette Jackson, Trial Manager, colette.jackson@nictu.hscni.net
Professor Noemi Lois, Chief Investigator, at n.lois@qub.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Colette Jackson

ORCID ID
https://orcid.org/0000-0001-7814-0749

Contact details
Northern Ireland Clinical Trials Unit
7 Lennoxvale
Belfast
United Kingdom
BT9 5BY
-
colette.jackson@nictu.hscni.net

Type(s)
Scientific, Principal investigator

Contact name
Prof Noemi Lois

ORCID ID
https://orcid.org/0000-0003-2666-2937

Contact details
The Wellcome-Wolfson Institute for Experimental Medicine, Queen’s University Belfast, 97 Lisburn Road
Belfast
United Kingdom
BT9 7BL
-
n.lois@qub.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
338079

Central Portfolio Management System (CPMS)
60043

Study information

Scientific Title
COMBAT: Clinical- and cost-effectiveness, safety and acceptability of COMBined phacovitrectomy, versus sequentiAl viTrectomy and cataract surgery, for the management of rhegmatogenous retinal detachment: A Randomised Equivalence Clinical Trial

Acronym
COMBAT

Study objectives
Aim
To determine whether, in people with non-highly myopic phakic rhegmatogenous retinal detachment (RRD) (Population), phacovitrectomy (Intervention) is equivalent (equivalence margin +/- 7 Early Treatment Diabetic Retinopathy Study ETDRS letters) to vitrectomy and subsequent cataract surgery (phacoemulsification) if/when needed (Comparator) for improving vision following surgery (primary Outcome) but superior for other (secondary) outcomes (as listed in this protocol) in the 52 weeks (+/- 6 weeks) after surgery.

Objectives
To determine if, in people presenting with non-highly myopic phakic RRD, phacovitrectomy (i.e. removing the cataract and doing vitrectomy to repair the RRD) is as good or better as doing only the retinal detachment repair with vitrectomy and then, if and when the cataract develops, doing a phaco (i.e. cataract surgery) and to assess post-trial implementation strategies and scalability.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/03/2025, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, United Kingdom; +44 2071048100; leedswest.rec@hra.nhs.uk), ref: 25/YH/0056

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rhegmatogenous retinal detachment

Interventions
Following consent, participants will be reviewed by the research team, including their surgeon. Previous medical and eye history will be reviewed, and measurements of the eye and baseline data (including 5 questionnaires) will then be collected. Patients will then be seen again at 1, 6, 12, and 52 weeks (+/- 6 weeks) post-surgery for the measurements and baseline data collection. Participation in the study will end following the 52-week visit.

Participants will also have the option at their initial study discussion to give consent to be contacted in the future to take part in individual interviews to talk about their opinions and experiences of treatment. The study PPI group gave favorable feedback about the proposed options for the consenting process (written/verbal) for interviews. Participants can receive an audio recording of their consent if they request this. A total of 3 (maximum) individual interviews will be undertaken by the participant.

Health care professionals will also be invited to give online consent to take part in an individual /small group discussion to share their views on the barriers and facilitators involved in the implementation of the COMBAT study.

Studies within a Trial (SWAT)
There will be 2 SWATs embedded in the trial:

SWAT A - Will record the proportion in each of the demographic groups who are recruited and retained at each site. We will also collect information over the course of the trial on how often the translated PIL are used and whether people for whom these are used are recruited and retained.

SWAT B - Sites who are willing to take part will evaluate whether an EDI-informed PIL increases the recruitment of underserved groups compared to the standard PIL. The exact content of the modified PIL is dependent on qualitative, diverse PPI work to be done during (around) the first year of the COMBAT study.

Timeline
The total study duration will be 48 months:
Months 1-6: Set up activities.
Months 7-15: Pilot Phase - Opening site, recruitment, data collection & follow-up, qualitative small discussions/interviews tasks.
Months 16-30: Main Study - Opening site, recruitment, data collection & follow-up, qualitative small discussions/interviews tasks.
Months 31-42: Follow-up, data cleaning, qualitative small discussions/interviews tasks.
Months 43-48: Write-up, reporting, and dissemination.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Change in Best-Corrected Visual Acuity (BCVA) in the study eye from baseline to 52 weeks (+/- 6 weeks) after surgery (equivalence margin +/- 7 ETDRS letters).

Key secondary outcome(s)
1. Primary anatomical success is measured using retinal attachment status at 52 weeks (+/- 6 weeks) after one vitrectomy
2. Final anatomical success is measured using retinal attachment status at 52 weeks (+/- 6 weeks) after two or more vitrectomies
3. Intraoperative complications are measured using severity score during surgery
4. Postoperative complications are measured using severity score at 52 weeks (+/- 6 weeks) after surgery
5. Number and type of surgeries performed are measured using surgical records at 52 weeks (+/- 6 weeks) after surgery
6. Refractive error is measured using the difference between aimed and obtained post-operative refraction at 12 weeks after surgery in the phaco-vitrectomy arm and 6-8 weeks post-cataract surgery in the vitrectomy only arm
7. Proportion of participants with BCVA <69 letters is measured using BCVA test at 52 weeks (+/- 6 weeks) after surgery
8. Proportion of participants with BCVA <34 letters is measured using BCVA test at 52 weeks (+/- 6 weeks) after surgery
9. Time to achieve 'best vision' is measured using BCVA test at baseline and 52 weeks (+/- 6 weeks) after surgery
10. Change in BCVA from baseline over time is measured using BCVA test at baseline and 52 weeks (+/- 6 weeks) after surgery
11. Health-related quality of life is measured using EuroQol-5 level (EQ-5D-5L) at baseline and 52 weeks (+/- 6 weeks) after surgery
12. Vision-specific quality of life is measured using the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) at baseline and 52 weeks (+/- 6 weeks) after surgery
13. Participant's experience and acceptability of treatments are measured using questionnaires at 52 weeks (+/- 6 weeks) after surgery
14. Use of health and social care services and non-health care is measured using questionnaires at 52 weeks (+/- 6 weeks) after surgery
15. Safety is measured using AE/SAE reporting at 52 weeks (+/- 6 weeks) after surgery

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Adults ≥50 years of age
2. Non-highly myopic (< -6 diopters; ≤26.5 mm axial length) phakic RRD
3. Naïve to previous vitreoretinal surgery
4. Pars plana vitrectomy is planned to repair their RRD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Presence of a “formed/established cataract.” A “formed/established cataract” is defined as a cataract that, based on the Age-Related Eye Disease Study (AREDS)
Research Group, is graded as nuclear sclerosis of >3 and/or if there is an anterior cortical cataract and/or a
subcapsular posterior cataract involving the visual axis.
2. Pseudophakia or aphakia.
3. High myopia (≥ -6 diopters; >26.5 mm axial length).
4. Giant retinal tear (i.e. presence of one or more retinal tears of >3 clock hours in size)
5. Retinal dialysis
6. Inclusion in an investigational drug study
7. Declined consent for participation

Date of first enrolment
09/05/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road

Belfast
Northern Ireland
BT9 7AB

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
England
BD9 6RJ

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
England
SE5 8AB

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool

England
L7 8XP

Study participating centre
Buckinghamshire Healthcare NHS Trust
Amersham Hospital
Whielden Street
Amersham
England
HP7 0JD

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
London
England
EC1V 2PD

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Sandwell and West Birmingham Hospitals NHS Trust
City Hospital
Dudley Road
Birmingham
England
B18 7QH

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

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

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
Lyndhurst Road
Worthing
England
BN11 2DH

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

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
England
SS0 0RY

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
Scotland
G12 0XH

Study participating centre
Queen's University Belfast
Centre for Public Health
Belfast
Northern Ireland
BT7 1NN

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
England
CH49 5PE

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Imperial College NHS Trust - Western Eye Hospital
Western Eye Hospital,
Marylebone Road
London
England
NW1 5QH

Study participating centre
NHS Lothian - Princess Alexandra Eye Pavilion
Princess Alexandra Eye Pavilion,
Chalmers Street
Edinburgh
Scotland
EH3 9HA

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
University/education

Funder Name
Queen's University Belfast

Alternative Name(s)
QUB

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Following publication of the primary and secondary outcomes and after data has been fully exploited by the COMBAT research team, there may be scope to conduct additional analyses on the data collected. In such instances, formal requests for data will need to be made in writing to

the CI via the NICTU. If there are requests for data sharing, these will be reviewed on a case-by-case basis by the CI and NICTU (Northern Ireland Clinical Trials Unit, 7 Lennoxvale, Belfast) with approval by the Sponsor required before data are shared.

IPD sharing plan summary

Available on request