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# 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**
08/05/2025

**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

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Public

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
338079

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

### Study design
Interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
To follow

## 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 measure
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).

## Secondary outcome measures
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

## Overall study start date
01/11/2024

### 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

### Age group
Adult

### Lower age limit
50 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 276; UK Sample Size: 276

### 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
England

Northern Ireland

Scotland

United Kingdom

**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**
**Barts Health NHS Trust**
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

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

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

**Study participating centre**
**Kings College Hospital**
Mapother House

De Crespigny Park
Denmark Hill
London
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SE5 8AB

**Study participating centre**
**Liverpool University Hospitals NHS Foundation Trust**
Royal Liverpool University Hospital
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L7 8XP

**Study participating centre**
**Buckinghamshire Healthcare NHS Trust**
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Whielden Street
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United Kingdom
HP7 0JD

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

**Study participating centre**
**Hull University Teaching Hospitals NHS Trust**
Hull Royal Infirmary
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Hull
United Kingdom
HU3 2JZ

**Study participating centre**
**Manchester University NHS Foundation Trust**
Cobbett House

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

**Study participating centre**
**Oxford University Hospitals NHS Foundation Trust**
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Headley Way
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OX3 9DU

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

**Study participating centre**
**Sheffield Teaching Hospitals NHS Foundation Trust**
Northern General Hospital
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S5 7AU

**Study participating centre**
**South Tees Hospitals NHS Foundation Trust**
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TS4 3BW

**Study participating centre**
**South Tyneside and Sunderland NHS Foundation Trust**
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SR4 7TP

**Study participating centre**
**Leeds Teaching Hospitals NHS Trust**
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**Study participating centre**
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**Study participating centre**
**The Royal Wolverhampton NHS Trust**
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**Study participating centre**
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**Sponsor type**
University/education

**Website**
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**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

### Publication and dissemination plan
The study will be used to inform participants and public, clinicians and policy makers of the best options available to treat people who present with phakic, non-highly myopic RRD. The results of COMBAT will be disseminated widely through presentations at national and international ophthalmology meetings and in invited lectures. The results will be presented at participant group meetings. The COMBAT PPI Group will contribute to the dissemination efforts to ensure the results are available to participants, their families, and the public. The research team includes lead clinicians and researchers with contacts across the world. They will use these international contacts to ensure trial results are disseminated widely and incorporated into future guidelines on the management of RRD. COMBAT will be reported in accordance with the CONSORT guideline (43). If necessary, the CONSORT and SPIRIT Extension for RCTs Revised in Extenuating Circumstances (CONSERVE) statement will be applied if extenuating circumstances require major modifications to the trial. The protocol, SAP and HEAP will be made publicly available to ensure transparency in the methods used in the study.
In accordance with the open access policies proposed by the NIHR, we plan to publish the clinical findings of the trial as well as a separate paper describing the health economic findings in high quality, high impact, peer reviewed open access journals. Other papers are planned (e.g. to present data on patient experience and acceptability of the treatments, and the results of the SWAT, among others).
We will actively promote the findings of the study to journal editors and opinion leaders in ophthalmology to ensure findings are widely disseminated (e.g. through editorials and conference presentations) and are included in future guidelines. The most significant results will be communicated to the wider public through media releases. An ongoing update of the study will be provided on the NICTU website.

### Intention to publish date

### 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