

# 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

<b>Submission date</b> 11/04/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/04/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/05/2025	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:colette.jackson@nictu.hscni.net)  
Professor Noemi Lois, Chief Investigator, at [n.lois@qub.ac.uk](mailto: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](mailto: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](mailto:n.lois@qub.ac.uk)

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

338079

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

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

## **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  $\geq 50$  years of age
2. Non-highly myopic (< -6 diopters;  $\leq 26.5$  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**

Adult

**Lower age limit**

50 years

**Sex**

All

**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 ( $\geq -6$  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  
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  
United Kingdom  
SE5 8AB

**Study participating centre**

**Liverpool University Hospitals NHS Foundation Trust**  
Royal Liverpool University Hospital  
Prescot Street  
Liverpool

United Kingdom  
L7 8XP

**Study participating centre**

**Buckinghamshire Healthcare NHS Trust**  
Amersham Hospital  
Whielden Street  
Amersham  
United Kingdom  
HP7 0JD

**Study participating centre**

**County Durham and Darlington NHS Foundation Trust**  
Darlington Memorial Hospital  
Hollyhurst Road  
Darlington  
United Kingdom  
DL3 6HX

**Study participating centre**

**Hull University Teaching Hospitals NHS Trust**  
Hull Royal Infirmary  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**

**Manchester University NHS Foundation Trust**  
Cobbett House  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**

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

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

**Study participating centre**

**Sandwell and West Birmingham Hospitals NHS Trust**

City Hospital

Dudley Road

Birmingham

United Kingdom

B18 7QH

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Northern General Hospital

Herries Road

Sheffield

United Kingdom

S5 7AU

**Study participating centre**

**South Tees Hospitals NHS Foundation Trust**

James Cook University Hospital

Marton Road

Middlesbrough

United Kingdom

TS4 3BW

**Study participating centre**

**South Tyneside and Sunderland NHS Foundation Trust**

Sunderland Royal Hospital

Kayll Road

Sunderland

United Kingdom

SR4 7TP

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

St. James's University Hospital

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

**Study participating centre**

**The Royal Wolverhampton NHS Trust**

New Cross Hospital

Wolverhampton Road

Heath Town

Wolverhampton

United Kingdom

WV10 0QP

**Study participating centre**

**University Hospital Southampton NHS Foundation Trust**

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

**Study participating centre**

**University Hospitals Bristol and Weston NHS Foundation Trust**

Trust Headquarters

Marlborough Street

Bristol

United Kingdom

BS1 3NU

**Study participating centre**  
**University Hospitals Dorset NHS Foundation Trust**  
Management Offices  
Poole Hospital  
Longfleet Road  
Poole  
United Kingdom  
BH15 2JB

**Study participating centre**  
**University Hospitals of Leicester NHS Trust**  
Leicester Royal Infirmary  
Infirmary Square  
Leicester  
United Kingdom  
LE1 5WW

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

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

**Study participating centre**  
**University Hospitals Plymouth NHS Trust**  
Derriford Hospital  
Derriford Road  
Derriford

Plymouth  
United Kingdom  
PL6 8DH

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

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

**Study participating centre**  
**Queen's University Belfast**  
Centre for Public Health  
Belfast  
United Kingdom  
BT7 1NN

**Study participating centre**  
**Royal Berkshire NHS Foundation Trust**  
Royal Berkshire Hospital  
London Road  
Reading  
United Kingdom  
RG1 5AN

## **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