

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 Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/04/2025	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 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)

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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 hypothesis

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

Condition

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

Overall study end date

31/10/2028

Eligibility

Participant 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

Participant 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

Recruitment start date

01/05/2025

Recruitment end date

30/04/2027

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Study participating centre

Belfast Health and Social Care Trust

Trust Headquarters

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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

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BD9 6RJ

Study participating centre

Guys and St Thomas' NHS Foundation Trust

249 Westminster Bridge Road

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SE1 7EH

Study participating centre

Kings College Hospital

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SE5 8AB

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Study participating centre
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Study participating centre
County Durham and Darlington NHS Foundation Trust
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DL3 6HX

Study participating centre
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Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
162 City Road
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Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
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
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
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SR4 7TP

Study participating centre

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital
Beckett Street
Leeds
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LS9 7TF

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital
Freeman Road
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Study participating centre

The Royal Wolverhampton NHS Trust

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Study participating centre

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Study participating centre

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Sponsor information

Organisation

Queen's University Belfast

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Sponsor type

University/education

Website

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

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