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A study comparing retinal detachment surgery with and without a gas bubble injection before surgery

Submission date
26/10/2026

Recruitment status
Not yet recruiting

Registration date
20/11/2026

Overall study status
Ongoing

Last Edited
20/11/2026

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 located at the back of the eye is an important structure for sight. The macula at its centre is essential for sharp vision used in reading and recognising faces. Retinal detachment (RD) is a sight-threatening emergency where the retina pulls away from the back of the eye. Without quick treatment, it can cause permanent sight loss. In about half of cases, the macula is also detached , reducing the chance of visual recovery.
Surgery is the only way to fix retinal detachment. The most common method is pars plana vitrectomy (PPV), where the gel-like substance (vitreous) inside the eye is removed, the retina is repaired using laser or freezing treatment, and gas or oil maybe added to support healing. Although effective, vitrectomy is often delayed due to limited resources or the need to transfer patients to specialist care centres. New research suggests surgery within 3 days offers better visual outcomes than the traditional 7 day window. This creates pressure on NHS services, and so there is an urgent need for new treatments that can care for patients while they wait for surgery. TemPeST describes a treatment and care plan during the period between diagnosis of retinal detachment and surgery. This involves a small volume of gas being injected into the eye shortly after diagnosis, followed by patients needing to avoid making certain head movements or sleeping in specific ways until surgery. The aim of this is to stabilise the retina and protect the macula while the patient waits for surgery. The study aims to test whether it is possible and safe to run a larger clinical trial comparing TemPeST followed by surgery versus waiting for surgery alone.

Who can participate?
Patients aged 18 years and over who present to Moorfields Eye Hospital or Southend Eye Casualty with retinal detachment (macula also detached)

What does the study involve?
Participants will be randomly allocated to receive TeMPeST and then surgery or to have surgery alone. All participants will undergo surgery within 7 days and will be followed up for 6 months, collecting information about safety, participation, visual outcomes and how the trial process works.

What are the possible benefits and risks of participating?
All participants will undergo vitrectomy as part of routine care, and participation will not delay or withhold necessary surgery. For participants allocated to TemPeST, the temporary gas bubble may cover the retinal tear and allow fluid beneath the retina to be absorbed, potentially enabling the macula to reattach before vitrectomy. This may limit further deterioration in vision while awaiting surgery and could improve the potential for visual recovery. However, the study is not large enough to determine whether these potential benefits occur.
Participants in both groups may benefit from being monitored closely during the study, although most of their clinical care would also be provided routinely. The outcome of the trial may benefit future patients by determining whether a larger trial of TemPeST is feasible and justified and by improving understanding of the treatment and recovery of macula-off retinal detachment.
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Additional risks may apply to participants allocated to TemPeST, who will undergo an intravitreal gas injection and anterior chamber paracentesis, in which a small amount of fluid is drained from the front of the eye to help control eye pressure. These procedures may cause temporary discomfort, redness or bleeding on the surface of the eye. Potentially serious complications include raised or low eye pressure, inflammation, infection inside the eye, bleeding inside the eye, damage to the lens, cataract development or progression, new retinal tears, worsening of the retinal detachment or migration of gas beneath the retina. Raised eye pressure may impair blood flow through the central retinal artery. Complications may require additional medication or procedures and, in severe cases, may cause permanent loss of vision. The temporary gas injection may also fail to stabilise the retina before vitrectomy.
The gas bubble will temporarily affect vision and impose restrictions on travel and anaesthesia. Participants must not fly, travel to high altitude or receive nitrous oxide, including Entonox, while gas remains in the eye.
Risks will be minimised through defined eligibility criteria, assessment of contraindications and delivery by appropriately trained clinicians using aseptic technique. Anterior chamber paracentesis will be performed as specified in the protocol, and central retinal artery perfusion will be checked after gas injection. Further pressure-relieving treatment will be provided immediately if perfusion is impaired. Eye pressure and retinal status will be monitored, including at the additional safety review approximately 24 hours after injection. Participants will receive clear safety information, a gas warning alert and instructions about when and how to obtain urgent clinical advice. Adverse events will be recorded and reviewed through the study's safety-monitoring and oversight arrangements.
Preoperative positioning may cause neck, back or joint discomfort, difficulty sleeping, fatigue, anxiety or disruption to usual activities. Participants receiving TemPeST will receive clear instructions to maintain a face-down position for four hours, followed by upright positioning, avoiding backward head tilt or lying face-up until surgery. Participants may contact the study team if they experience difficulty. They may stop positioning or withdraw from the research without affecting their clinical care; any difficulties or changes will be documented and clinically reviewed.
Participants in both groups may experience inconvenience or fatigue from additional assessments, questionnaires and follow-up. Visits will be aligned with routine care wherever possible, questionnaires will be kept brief, and assistance and rest breaks will be offered, particularly because participants have impaired vision. Participant materials will be provided in accessible formats.

There is no guarantee of direct benefit, and random allocation may be disappointing to some participants. This will be explained during consent.

Where is the study run from?
Moorfields Eye Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2026 to March 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
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68878

National Institute for Health and Care Research (NIHR)
508124

Study information

Scientific Title
Temporising Pneumatic Supplementary Tamponade (TemPeST): a multicentre, single-masked, randomised controlled feasibility trial of pre-operative intravitreal perfluoropropane gas tamponade prior to pars plana vitrectomy for macula-off rhegmatogenous retinal detachment

Acronym
TemPeST

Study objectives
Is it feasible and acceptable to conduct a larger clinical trial comparing a temporary gas bubble followed by vitrectomy with vitrectomy alone in adults with a retinal detachment involving the central part of the retina?

The study will assess whether eligible patients can be recruited, allocated at random, treated and followed up successfully; whether participants can follow the required head-positioning instructions; whether the intervention and study procedures are acceptable to participants; and

whether the necessary clinical and research information can be collected reliably. It will also collect preliminary information about safety, vision and retinal outcomes to help design a future larger trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Macula-off rhegmatogenous retinal detachment

Interventions
TemPeST is a two-centre randomised feasibility study involving 60 adults with a retinal detachment affecting the macula, the central part of the retina responsible for detailed vision. Participants will be scheduled for primary vitrectomy within 7 days of presentation. Patients scheduled for surgery on the day of presentation will not be eligible.

Potential participants will first be assessed to confirm eligibility. A member of the research team will explain the study and provide written information. Patients who wish to participate will provide written informed consent before any research-specific procedures take place.

At baseline, information will be collected about the participant’s general characteristics, medical and eye history, and duration of central vision loss. Assessments will include vision testing with and without a pinhole, eye-pressure measurement, an eye examination and optical coherence tomography (OCT), a non-invasive scan of the retina. Participants will also complete the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) about how their vision affects everyday activities.

Participants will then be allocated at random in a 2:1 ratio to one of two groups:
1. TemPeST followed by vitrectomy: participants will receive an injection of 0.3 ml of pure perfluoropropane (C_3F_8)
gas into the affected eye using local anaesthetic. A small amount of fluid will be drained from the front of the eye to help control eye pressure, and blood flow through the central retinal artery will be checked afterwards. Participants will maintain a face-down position for four hours, followed by upright positioning, avoiding backward head tilt or lying face-up until surgery. They will attend a safety review approximately 24 hours after the injection, including vision testing, eye-pressure measurement, an eye examination, OCT imaging and a questionnaire about positioning adherence and acceptability.
2. Standard care: participants will not receive the temporary gas injection and will proceed to vitrectomy according to usual clinical practice.

All participants will undergo a preoperative assessment, including vision testing, eye-pressure measurement, an eye examination and OCT imaging. For participants receiving TemPeST, this may coincide with the 24-hour safety review.

All participants will undergo vitrectomy as their definitive treatment. Surgery will be planned within seven days of presentation, and participation will not delay clinically necessary surgery. The surgical technique and any postoperative positioning instructions will be determined by the treating surgeon.

Following vitrectomy, participants in both groups will attend follow-up visits at Week 1, Week 6, Month 3 and Month 6. Vision and eye pressure will be measured, the eye will be examined, and complications, additional treatment and further procedures will be recorded. OCT imaging will be performed at Week 6, Month 3 and Month 6.

At Months 3 and 6, participants will also undergo fundus autofluorescence imaging to assess retinal displacement, M-chart testing to measure distortion of vision, and the NEI VFQ-25 questionnaire. At Month 6, vision will additionally be measured following refraction to determine the best spectacle correction, and participants will complete a questionnaire about positioning, gas-related restrictions and acceptability, as applicable to their treatment.

Participation will end after the 6-month assessment. The findings will help determine whether a larger trial is feasible and inform its design.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Proportion of eligible patients who can be successfully recruited, randomised, and retained to 6-month follow-up within NHS vitreoretinal services; Timepoint(s): 6 months

Key secondary outcome(s)
1. Protocol adherence, defined by successful intravitreal gas delivery,completion of the prescribed positioning regimen, and protocol-compliant surgical timing
2. Data completeness, measured by the proportion of complete datasets for best-corrected visual acuity (BCVA), OCT-based anatomical measures, and patient-reported outcomes (NEI VFQ-25 and acceptability questionnaires)
3. Safety profile, capturing the incidence, nature, and severity of adverse and serious adverse events, particularly intraocular pressure elevation, cataract progression, subretinal gas, and

reoperation, with monitoring in accordance with Good Clinical Practice
4. Acceptability, encompassing both patient and clinician perspectives on the TemPeST procedure and trial processes, evaluated through structured questionnaires addressing comfort, perceived safety, and ease of positioning
5. Exploratory clinical outcomes,including preliminary estimates of change in BCVA, metamorphopsia (M-charts), macular reattachment on OCT, and NEI VFQ-25 quality-of-life scores at 6 months to provide early estimates of effect size and variance
6. Operational feasibility, capturing process-level indicators of trial delivery such as screening efficiency, time from identification to consent, reasons for non-participation or withdrawal, and procedural timing

Timepoint(s): 6 months

Completion date
31/03/2028

Eligibility

Key inclusion criteria
1. Adults aged ≥18 years
2. Macula-off rhegmatogenous retinal detachment in the study eye
3. Planned primary pars plana vitrectomy repair within 7 days of presentation in the study eye
4. Able to provide informed consent
5. Sufficient visual function in at least one eye to engage with study procedures and positioning requirements

Stratification: By recruiting site and symptom duration

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previous vitreoretinal surgery in the study eye
2. Proliferative vitreoretinopathy grade C or greater in the study eye
3. Giant retinal tear in the study eye

4. Significant ocular infection or inflammation in the study eye
5. Inability to safely comply with positioning requirements
6. Contraindication to intravitreal gas injection
7. Participation or planned participation in another interventional ophthalmic trial involving an investigational medicinal product, device or ocular procedure from 30 days before randomisation until the end of the 6-month TemPeST follow-up
8. Planned primary pars plana vitrectomy on the same day as presentation in the study eye

Date of first enrolment
01/12/2026

Date of final enrolment
31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Moorfields Eye Hospital NHS Foundation Trust
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Study participating centre
Mid and South Essex NHS Foundation Trust
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Sponsor information

Organisation
Moorfields Eye Hospital NHS Foundation Trust

ROR
https://ror.org/03zaddr67

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date