ISRCTN29200092 https://doi.org/10.1186/ISRCTN29200092

Temporary gas injection into the eye to help stabilize the retina in adults with retinal detachment before vitrectomy surgery

Submission date
03/10/2025

Recruitment status
Recruiting

Registration date
10/10/2025

Overall study status
Ongoing

Last Edited
02/09/2026

Condition category
Eye Diseases

[ ] 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
Retinal detachment affecting central vision causes a decrease in visual acuity, often leaving permanent damage. The usual treatment for this type of detachment is an eye surgery called “vitrectomy”, which is done in the operating room.
There is a technique called pneumatic retinopexy, consisting of injecting an air bubble in the eye. This gas injection allows the retina to start to reattach until the day of the operation by keeping the face downwards (see next image). This technique is often used when the detachment is partial, and/or when there is only one tear in the superior part of the retina. When retinal detachments are more complex (many tears, inferior detachment, etc.), the vitrectomy remains the operation of choice.
As of right now, we do not know whether pneumatic retinopexy before the operation can benefit visual acuity in the long run. This is the reason why it is not used routinely in clinical practice.
The objective of this research project is to determine whether pneumatic retinopexy done before the operation gives a better long-term vision for people with a retinal detachment.

Who can participate?
The study is for patients aged 30 - 90 years, experiencing a retinal detachment affecting the center of vision.

What does the study involve?
The study involves the injection of a gas bubble in the eye before performing the surgery to resolve the retinal detachment more permanently. Participants will be randomly assigned to group A or group B, with group A receiving the injection of gas and the group B not receiving the injection.

What are the possible benefits and risks of participating?
You may benefit personally from participating in this research project, but we cannot guarantee it. Furthermore, we hope that the results obtained will contribute to the advancement of scientific knowledge in this area and to the development of better treatments for patients.

1. Risks associated with the study procedure (group 1 only)
Injection of gas (pneumatic retinopexy)
• Temporary increase in intraocular pressure after the procedure (expected and monitored, close to 100%)
• Progression of cataracts (20% risk)
• Formation of new retinal tears at the periphery of the retina (15% risk)
• Increase in the percentage of scars forming on the retina (4% risk)
• Passage of gas under the retina, which could further detach the retina (less than 1% risk)
• Infection in the eye (less than 0,1% risk)
Local anesthetic (0.5% tetracaine drops)
• Temporary burning or stinging sensation, redness, tearing (75% risk)
• Reduced sensation of the cornea (expected effect), which can increase risks of corneal abrasion by rubbing (risk possible if eye rubbing)
• Allergic reaction (less than 1% risk)
If the surgeon decides to use sub-conjunctival anesthesia (an injection of 2% lidocaine on the surface of the eye), the risks of the injection are:
• Pain and pressure at the injection site (75% risk)
• Sub-conjunctival hemorrhage, a self-resolving benign bleeding which can be cosmetically noticeable, or swelling of the conjunctiva of the eye (30%)
• Perforation of the eye, infection in the eye (extremely rare, less than 0.01%)
And the risks associated with the anesthetic injected at the surface of the eye are:
• Allergic reaction or systemic reaction to the anesthetic (rare cases documented for this type of administration)
It is also uncomfortable to keep the head facing downwards until the surgery.

Where is the study run from?
The study is run in only one hospital, Hôpital Maisonneuve-Rosemont in Montreal, Quebec, Canada. All personnel work at this clinic and all patients will be recruited from the same clinic.

When is the study starting and how long is it expected to run for?
The study is starting in October 2025 and is expected to run until August 2027, depending on the number of patients recruited.

Who is funding the study?
Université de Montréal Ophthalmology Research Fund (Canada)

Who are the main contacts
Shigufa K Ali, shigufa.kahn.ali.cemtl@ssss.gouv.qc.ca

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Cynthia X. Qian

Contact details
5415 Assomption Blvd, Montreal, Quebec
Montreal
Canada

H1T 2M4
+1 514-252-3400 poste 4948
cynthia.xin-ya.qian@umontreal.ca

Type(s)
Public

Contact name
Ms Shigufa K. Ali

Contact details
5415 Assomption Blvd, Montreal, Quebec
Montreal
Canada
H1T 2M4
+1 514-252-3400 poste 4948
shigufa.kahn.ali.cemtl@ssss.gouv.qc.ca

Additional identifiers

Protocol serial number
2024-3514

Study information

Scientific Title
Preoperative C3F8 injection as a temporary macular tamponade in macula-off rhegmatogenous retinal detachments in candidates to pars plana vitrectomy

Acronym
REMAC

Study objectives
The goal of this clinical trial is to learn if a gas injection in the eye before surgery can help long-term vision in retinal detachments affecting the center of vision in adult patients aged 30-90 years.

The main question it aims to answer is: Does a gas injection in the eye before surgery improve long-term vision compared to surgery alone?

Researchers will compare the gas injection followed by surgery to surgery alone to see if long-term vision is improved by the gas injection.
Participants will either receive the gas injection followed by surgery as scheduled, or proceed to the surgery as scheduled. Patients receiving the gas injection will remain face-down until the surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 23/09/2025, Research Ethics Committee of the CIUSSS Est-de-l'Île-de-Montréal (5415, boul. de l'Assomption Montréal (Québec), Montreal, H1T 2M4, Canada; +1 514 252-3400, extension 5708; cer.cemtl@ssss.gouv.qc.ca), ref: 2024-3514

Primary study design
Interventional

Study design
Single center 2 arm open-label randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rhegmatogenous Retinal Detachment - Macula Off

Interventions
Intervention: pneumatic retinopexy of C3F8 before vitrectomy surgery
Control: vitrectomy surgery only

The date of the vitrectomy is independent of the treatment arm.

1:1 randomization with randomization.net

Intervention Type
Procedure/Surgery

Primary outcome(s)
Visual acuity measured using ETDRS letters at 3 months

Key secondary outcome(s)
1. Macular reattachment rate measured by the proportion of macular reattachment in both groups at 3 months
2. Presence of new tears measured using proportion of patients with new tears at 3 months
3. New or progression of proliferative vitreoretinopathy measured using rate of PVR developing or progression (using standard PVR grading) at 3 months.
4. Accordance of tamponade selection using accordance ratio of preoperative assessments and actual tamponade use at time of surgery.
6. Retinal displacement rate measured in proportion at 3 month
7. Number of total surgeries needed at 3 months

Completion date
30/08/2027

Eligibility

Key inclusion criteria
1. Age 30-90 years old
2. Primary macula-off rhegmatogenous retinal detachment with a maximum 2 weeks (14 days) of central vision loss at presentation

3. Rhegmatogenous retinal detachment not suitable for pneumatic retinopexy alone without vitrectomy because of extension, multiple tears, inferior localization or multiple lattice

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Proliferative vitreoretinopathy grade B or C
2. Tractional or serous detachments
3. Presence of other ophthalmological diseases that have an effect on visual acuity (potential confounders): terminal glaucoma, neuropathy, history of posterior uveitis, previous macular pathology
4. Macula-split retinal detachments
5. Patients not able to maintain postoperative positioning
6. Patients who present with a central vision loss of more than 2 weeks (14 days)

Date of first enrolment
03/10/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital Maisonneuve-Rosemont
5415 Assomption Blvd, Montreal, Quebec
Montreal

Canada
H1T 2M4

Sponsor information

Organisation
Hôpital Maisonneuve-Rosemont

ROR
https://ror.org/03rdc4968

Funder(s)

Funder type
University/education

Funder Name
Université de Montréal Ophthalmology Research Fund

Results and Publications

Individual participant data (IPD) sharing plan
De-identified individual participant data (IPD) may be made available upon reasonable request after publication of the primary results and with appropriate data-use agreements, including ethics board approval.

IPD sharing plan summary
Available on request