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Use of subtenon triamcinolone acetonide for a dropless trabeculectomy surgery

Submission date	**Recruitment status**	[X] Prospectively registered
27/12/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/01/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/01/2023	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Glaucoma is a common eye condition where the optic nerve, which connects the eye to the brain, becomes damaged. It affects between 2.7 and 7.5% of the Canadian population older than 50 years old. Elevated intraocular pressure (IOP, the fluid pressure of the eye) highly influences progression rates and treatment of glaucoma is guided towards reducing IOP, which can involve pressure-reducing drops or intraocular (eye) surgery.

Trabeculectomy is the most frequently performed glaucoma surgical procedure, accounting for about 40% of interventions. In this surgery, aqueous humor (the clear liquid inside the front part of the eye) is diverted, reducing intraocular pressure. Inflammation and scar tissue formation play a significant role in the success of the surgery, and a strict steroid drop schedule is necessary for surgical success. However, adherence to the strict regimen of steroid drops after surgery is less than ideal, with around 20% of patients failing to regularly use their anti-inflammatory steroid drops, which is associated with worse long-time pressure results.

Deposit steroids can be a reliable and safe alternative to this strict steroid drop schedule. One alternative would be a sub-tenon triamcinolone acetonide (TAC) injection. Exclusive sub-tenon triamcinolone could provide several advantages over the conventional strict steroid drop regimen: (i) it is not dependent on patient adherence; (ii) it decreases the amount of preservative over the surgical site, as topical prednisolone administered every 2 hours delivers a high dose of preservatives, which are toxic and damaging to the eye; (iii) increased patient comfort due to avoiding the stinging and irritation caused by frequent drop instillations; (iv) potentially higher concentration of steroid. In addition, sub-tenon TCA stays in the tissues around the eye for about 3 months, which is the ideal time to prevent surgically induced scar tissue formation.

So far, no studies have evaluated solely using sub-tenon TAC for inflammation control after trabeculectomy. The aims of this study are to determine: (1) the safety of the exclusive use of sub-tenon TAC after trabeculectomy surgery and (2) to compare surgical results to the standard approach of prednisolone acetate drops every 2 hours for the first 2 weeks, followed by a slow taper for a total period of 10 weeks of treatment. This novel method of postoperative care using a readily available steroid frequently utilized in ophthalmology for other reasons can reduce the burden of a strict drop schedule for patients and possibly give equivalent or even better postoperative results.

Who can participate?
Patients aged 18 to 90 years old selected for trabeculectomy surgery

What does the study involve?
All participants will follow the same preoperative course as a regular patient performing a glaucoma filtration surgery. They will receive no postoperative drops besides their regular glaucoma medication, and surgery will be scheduled on the date available for their glaucoma surgeon. On the day of the surgery, the surgeon will do the surgery as initially scheduled. If no complications occur, the patient will be randomly allocated to be prescribed either the regular postoperative steroid drops or sub-tenon triamcinolone treatment. Both groups will also receive intracameral Vigamox and prescribed Atropine drops 1% daily for the first week. Patients will be followed in the study for 1 year after surgery, with recorded follow-up visits performed at 1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, and 1 year after surgery. Extra visits in between are allowed depending on the need identified by the attending physician.

What are the possible benefits and risks of participating?
This study has the benefit of increasing the predictability and comfort of post-operative glaucoma treatment. Instead of using a steroid drop every 2 hours during the first month of the postoperative period, with a taper afterwards, this study can provide patients with a safe and continuous deposit alternative.
There is a theoretical risk of excessive eye inflammation, increased ocular pressure, and a greater surgical failure with intraoperative triamcinolone without regular steroid drops. Therefore, as a regular follow-up, patients will be closely monitored for pressure and inflammation for the first month after surgery. Patients from both groups will also have access to an eye emergency clinic if they feel any excessive discomfort. The researchers will also actively call patients who fail to attend regular follow-ups.

Where is the study run from?
1. Eye Care Centre, Nova Scotia Health Authority (Canada)
2. Halifax Vision Centre (Canada)
3. Glaucoma Clinic at the University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
November 2022 to March 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Rodolfo Bonatti, rodolfo.bonatti@nshealth.ca

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
52363

Study information

Scientific Title
Safety and efficacy of dropless steroid trabeculectomy surgery

Study objectives
Subtenon triamcinolone acetonide after trabeculectomy surgery without additional steroid drops can provide an anti-inflammatory effect similar to a steroid drop schedule after the same surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Nova Scotia Health Authority

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pseudophakic patients undergoing trabeculectomy surgery

Interventions
After providing informed consent, all participants will follow the same pre-operative course as a regular patient undergoing glaucoma filtration surgery. They will receive no postoperative drops besides their regular glaucoma medication, and surgery will be scheduled on the date available

for their glaucoma surgeon. On the day of the surgery, the surgeon will do the surgery as initially scheduled. If no complications occur, the patient will be randomized to either regular postoperative drops or sub-tenon triamcinolone treatment.

Randomization: At the baseline visit, after the patient agrees to participate in the study, the surgeon performing the filtrating surgery will talk with the nurse or nurse assistant to randomize a number at the website "random.org". If the number is even, the surgeon will do a TAC injection (triamcinolone follow-up); if the number is odd, the surgeon will not do a TAC injection (regular follow-up).

1. Prednisolone acetate 1% or dexamethasone sodium phosphate 0.1% drops every 2 hours on the operated eye for 1 month, followed by a tapper reducing a drop a day every 2 weeks until no drops are used.
2. Triamcinolone acetonide 16 mg (4 ml of the 40 mg/ml solution) injected subtenon at the time of the surgery.

Both groups will be followed until the 1 year of follow-up. The recorded follow-up visits will be done on 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year after surgery. Doctors are free to schedule more follow-up dates if necessary.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Triamcinolone acetonide

Primary outcome(s)
The number of patients in the triamcinolone follow-up group that did not need steroid drops, recorded at the end of the study

Key secondary outcome(s)
1. Mean intraocular pressure (IOP) measured using applanation tonometry at follow-up visits at 1, 3, 6 months and 1 year after the surgery
2. The number of pressure-reducing drops measured using chart review at 3, 6, and 12 months after the surgery
3. Time to failure, defined by the need for any surgery for hypotony (pressure <5 mmHg) or for reducing pressure (IOP >21 mmHg or pressure reduction lower than 20% compared to baseline) during the duration of the study

Completion date
01/03/2025

Eligibility

Key inclusion criteria
1. Age 18 to 90 years old
2. Patients selected for trabeculectomy surgery
3. Pseudophakic patients or patients that will do a combined procedure with filtration glaucoma

surgery and will become pseudophakic
4. Ability to comprehend the study procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Key exclusion criteria
1. Unwilling or unable to give consent
2. Unable to come for scheduled postoperative visits
3. Patients that are known to be steroid responders (ocular hypertension with steroid use)
4. Presence of a condition that could affect inferior conjunctiva
5. Intraoperative complications: such as excessive hyphema, inability to perform a trabeculectomy flap, positive seidel, or posterior capsular rupture.
6. Pregnant or nursing women
7. No light perception vision
8. Active iris neovascularization or active proliferative retinopathy
9. Vitreous in the anterior chamber for which a vitrectomy is anticipated.
10. Previous cyclodestructive procedures, scleral buckling procedures, or silicone oil present
11. Conjunctival scarring precluding a trabeculectomy superiorly
12. Previous trabeculectomy or tube-shunt implantation

Date of first enrolment
01/03/2023

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
Canada

Study participating centre

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Sponsor information

Organisation
Nova Scotia Health Authority

ROR
https://ror.org/035gna214

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication