كـلية الطـب

Title : Gonioscopy-Assisted Transluminal Trabeculotomy in Pediatric Glaucoma Following Cataract Surgery

protocol record (MD-196-2024)

Date: 25 October 2025

جامعة القاهرة
كلية الطب

Code: MD-196-2024

Cairo University
Faculty of Medicine
Research Ethics Committee

NOTICE OF APPROVAL

Date: **25-10-2025**

Protocol title: **Outcome of Gonioscopy-Assisted Transluminal Trabeculotomy in glaucoma following pediatric cataract surgery. A Prospective interventional Case Series**

Supervisor: **Prof. Hala Mostafa Mohamed Elhilali**

Candidate: **Dr. Marwa Elsayed Soliman Ahmed**
Institution: **Cairo University**

Decision: APPROVAL

The Research Ethics Committee **(REC)** has reviewed and **approved** the above-mentioned **protocol. You may begin your investigation**. Approval is granted for one year from the date of initial approval. At the end of this period, the principal investigator will submit the required documents for continuing review.

The principal investigator will need to:

- Notify the REC Chair immediately after any **serious adverse events** experienced by participants of the investigational study or as reported to you by the sponsor/manufacturer/co- investigators.
- Submit End of trial notification at the end of trial.
- Submit Clinical study report at the end of trial.
- You may not initiate **changes** in approved research protocol without REC review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.
- يحظر سفر أي عينات بشريه من المبحوثين خارج جمهوريه مصر العربية الا بعد موافقة الجهات الامنية.

Sincerely,

REC Chairman

Prof. Maher Fawzy, MD

Maher Fawzy

Professor of Anaesthesia,

Cairo University

كـلية الطـب

Cairo University

KASR ALAINY
CAIRO UNIVERSITY - FACULTY OF MEDICINE

Faculty of Medicine, Cairo University Postgraduate Research Protocol Template

1. Study

a- Proposed Study Title: Outcome of Gonioscopy-Assisted Transluminal Trabeculotomy in glaucoma following pediatric cataract surgery. A Prospective interventional Case Series.
b- Degree: MD
c- Date of Registration of MD: March 2024

2. Candidate

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3. Supervisors Contact Information

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4. **Scientific committee approval**
(Was it scientifically approved by the department?)

Date of approval:

5. **Background and Rationale:** (Describe the research question and justification for undertaking the study explaining the aspects of novelty in the study)

Glaucoma following pediatric cataract surgery is a recognized postoperative complication that may require surgical management when medical therapy is insufficient. Gonioscopy-assisted transluminal trabeculotomy (GATT) is a minimally invasive conjunctiva-sparing procedure designed to improve aqueous outflow through circumferential trabeculotomy.

This prospective interventional case series will evaluate outcomes of GATT in eligible pediatric patients with glaucoma following cataract surgery treated at Cairo University Hospitals. Participants will undergo preoperative ophthalmic assessment, standardized surgical intervention, and scheduled postoperative follow-up visits. Outcomes to be assessed include intraocular pressure, use of glaucoma medications, and safety parameters during follow-up.

6. Objectives: (describe specific objectives or hypotheses behind the study)

- To evaluate the safety and effectiveness of gonioscopy-assisted transluminal trabeculotomy (GATT) in children with glaucoma following cataract surgery, with assessment of intraocular pressure control, postoperative medication requirements, and procedure-related complications..

7. Study Design: (Please fill in the appropriate study design, see attached PDF guide)

- Descriptive: - Survey (cross sectional) ☐
  - Qualitative ☐
- Analytic: - Observational: - Case-control study ☐
  - Cross sectional analytic study ☐
  - Cohort (Longitudinal) study ☐
  - Experimental: - Randomized Clinical Trial ☐ Phase:
  - Non-randomized clinical trial ☐
  - Animal study ☐
  - Cellular study ☐
- Others: Please describe: Prospective interventional Case Series.

8. Study Methods

Population of study:

- Patients presenting to the ophthalmology outpatient clinic of – Abuelresh - Cairo University Hospital with pediatric glaucoma following cataract surgery aging from 1-12 years.

Study location:

- The study will be conducted at Cairo University Hospitals.

- **Inclusion criteria:**
  - Patients with pediatric glaucoma following cataract surgery and clear corneas allowing visualization of the angle.
    Based on the Childhood Glaucoma Research Network(CGRN), GFCS is secondary glaucoma that meets glaucoma definition after cataract surgery is performed (Glaucoma: 2 or more of the following are required: (1) IOP >21 mm Hg (2) Visual fields: reproducible visual field defect that is consistent with glaucomatous optic neuropathy with no other observable reason for the visual field defect. (3) Axial length: progressive myopia or myopic shift with increased ocular dimensions that outpace normal growth. (4) Optic nerve: progressive increase in cup-to-disc ratio, cup-to-disc asymmetry ≥0.2 when optic discs are of similar size, and focal rim thinning.
  - Patients with pediatric glaucoma following cataract surgery and clear corneas allowing visualization of the angle who underwent previous glaucoma surgery.
- **Exclusion criteria: -**
  - Eyes with retinal pathology.
  - Eyes with synechial angle closure involving > 180 degrees of the iridocorneal angle.
- **Methodology in details:**
  - All selected patients' carers will receive a thorough explanation of the study design and aims and will sign an informed consent.

Pre-operative evaluation of all participants will include:

- Best corrected visual acuity (BCVA) using Snellen's chart whenever possible according to age.
- Central corneal thickness (CCT).
- Horizontal corneal diameter (HCD).
- Slit lamp examination of the anterior segment.
- Gonioscopy using Swan Jacob lens.
- Intraocular pressure measurement using Perkins applanation tonometry.
- Dilated fundus examination by binocular indirect ophthalmoscopy and slit-lamp bio-microscopy using +90 D Volk condensing lens.

Surgical technique:

GATT surgery:

- All surgeries will be performed under general anesthesia, The operating microscope is tilted 45 degrees,, the head of the bed is elevated, and the head of the patient is tilted to the opposite side. While sitting on the temporal side of the patient a temporal corneal incision is created by a 23 Gauge MVR. An inferior or superior paracentesis is created. The anterior chamber (AC) is filled using cohesive viscoelastic then the angle is visualized by direct gonioscopy using Swan Jacob lens. Nasal goniotomy for 2 clock is performed by using MVR blade to incise the inner wall of Schlemm's canal. Cohesive OVD is used to open the lips of the incision, then 5/0 prolene after being blunted by cautery pen is threaded inside Schlemm's canal guided it inside the canal using 23-gauge vitreoretinal forceps until we retrieve it from the opposite end of the incision. The two ends of the 5/0 prolene suture are pulled to incise the Schlemm's canal and trabecular meshwork over 360°.The AC is washed by BSS followed by injection of air to tamponade any bleeding then the wound is hydrated or sutured.

Post operative assessment:

At day 1, 1 week, 1month ,3months and 6 months.

- Each follow up visit will include slit lamp evaluation of the anterior segment, as well as IOP measurement using Perkins applanation tonometry with documentation of the antiglaucoma medications used. BCVA and cup-to-disc

ratio will be assessed at 1 month post-operative and will be compared at the final follow-up to the preoperative measurements.

- Surgical success will be defined as: *complete* if IOP is less than or equal to 21 mmHg without medications and *qualified* success if IOP is less than or equal to 21 mmHg with medications. Failure will be the inability to achieve such a pressure, the need for another glaucoma operation or the development of a sight-threatening complication (e.g. retinal detachment and endophthalmitis).

- **Intervention:**

☐ Diagnostic intervention

■ Therapeutic intervention (Gonioscopy-Assisted Transluminal Trabeculotomy in patients with pediatric glaucoma following cataract surgery).

☐ No intervention

- **Does the research involve?**

■ Human participants

☐ Biological samples/Tissues

☐ Identifiable private data/Information

- **Type of consent of study participants:**

■ Written consent

☐ Oral consent

☐ No consent needed (Please justify)

- **Potential risks:**

- Risks of surgery: hyphema, transient hypotony, corneal edema, anterior chamber inflammation, endophthalmitis, recurrence of IOP elevation, accidental IOL damage or iris injury

Confidentiality of data: All participants will be coded, and data entry will be using these codes.
All data of the patients will be saved in secure files.

9- Study outcomes:

- **Primary Outcome Measure**
- Change in intraocular pressure from baseline to 6 months postoperatively.
- Number of antiglaucoma medications required at 6 months.
- **Secondary Outcome Measures**
- Intraoperative and postoperative complications through 6 months.
- Need for additional glaucoma surgery through 6 months.
- Surgical success according to predefined study criteria at 6 months**.**

10- Sample size (number of study subjects included and justification including the clinical and statistical assumptions supporting sample size calculation)

- Sample size was estimated based on anticipated change in intraocular pressure from baseline after intervention, with statistical power of 90%, significance level of 0.05, and allowance for potential dropout. The planned enrollment is 20 participants.

11- Statistical analysis (Please describe your data analysis plan)

Statistical analysis will be conducted using SPSS 27th edition, categorical variables will be presented in count and percent and compared between groups using Fisher exact test. Quantitative variables will be presented in mean, standard deviation, minimum and maximum, it will be compared between groups using Student T test after

normality testing using Shapiro Wilk test. Correlation between two quantitative variables will be conducted using Pearson correlation test. Any p value <0.05 will be considered significant.

12- Source of funding: (Please include source of funding even if self-funding)

- Faculty of Medicine, Cairo University ■
- Other sources: ☐

  Please specify:

13- Time plan:

- When to start? Once the thesis is accepted by ethical committee
- When expected to finish? 20 months
- When to publish?

14- References:

1- Beck AC, Chang TC, Freedman SWeinreb RN, Grajewski A, Papadopoulos M, Grigg J, Freedman S. Section 1: Definition, classification, differential diagnosis. World Glaucoma Association Consensus Series–9: Childhood Glaucoma.
2- Beck AD, Freedman SF, Lynn MJ, Bothun E, Neely DE, Lambert SR, Infant Aphakia Treatment Study Group. Glaucoma-related adverse events in the Infant Aphakia Treatment Study: 1-year results. Archives of ophthalmology. 2012 Mar 12;130(3):300-5.
3- Freedman SF, Lynn MJ, Beck AD, et al. Glaucoma-related adverse events in the first 5 years after unilateral cataract removal in the Infant Aphakia Treatment Study. JAMA Ophthalmol. 2015;133:907–914.
4- Freedman SF, Beck AD, Nizam A, et al. Glaucoma-related adverse events at 10 years in the Infant Aphakia Treatment Study: a secondary analysis of a randomized clinical trial. JAMA Ophthalmol. 2021;139: 165–173.

5- Chen TC, Walton DS, Bhatia LS. Aphakic glaucoma after congenital cataract surgery. Archives of ophthalmology. 2004 Dec 1;122(12):1819-25.
6- Mandal AK, Netland PA. Glaucoma in aphakia and pseudophakia after congenital cataract surgery. Indian journal of ophthalmology. 2004 Jul 1;52(3):185-98.
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9- Gillmann K, Mansouri K. Minimally invasive glaucoma surgery: where is the evidence? Asia Pac J Ophthalmol (Phila). 2020;9:203–214.
10- Areaux RG Jr, Grajewski AL, Balasubramaniam S, et al. Trabeculotomy ab interno with the Trab360 device for childhood glaucomas. Am J Ophthalmol. 2020;209:178–186.
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12- Grover DS, Godfrey DG, Smith O, Feuer WJ, de Oca IM, Fellman RL. Gonioscopy-assisted transluminal trabeculotomy, ab interno trabeculotomy: technique report and preliminary results. Ophthalmology. 2014 Apr 1;121(4):855-61.
13- Quan AV, Chen J, Wang YE, Vanner EA, Grajewski AL, Hodapp EA, Chang TC. Factors associated with gonioscopy-assisted transluminal trabeculotomy (GATT) complications and failure in children. American journal of ophthalmology. 2022 Sep 1;241:168-78.

Ophthalmology sheet

Outcome of Gonioscopy-Assisted Transluminal Trabeculotomy in glaucoma following pediatric cataract surgery. A Prospective Case Series.

❖ Code:

1. Sociodemographic data:
   1.1 Gender:
   1.2 Age:

2. History:
   2.1 Age of cataract extraction.
   2.2 Any systemic co-morbidities.
   2.3 Any other ocular surgery.
   2.4 Any ocular Trauma.

3.Pre-operative Examination:

	2. OD	OS
3.1 UCVA		
3.2 BCVA		
3.3 Refraction		
3.4 Intraocular pressure		
3.5 Anterior segment examination		
3.6 Fundus examination		
3.7 Gonioscopy		
3.8 Automated perimetry		

4. Post-operative Examination Day 1, week 1, 1 month, 3 months, 6 months.

	3. OD	OS
4.1 UCDVA		
4.2 BCDVA		
4.3 refraction		
4.4 Intraocular pressure		
4.5 Anterior segment		
4.6 Anti glaucoma medications used		
4.7 Gonioscopy(starting from 1st month)		

Informed Consent Form

Study Title

GATT in Pediatric Glaucoma Following Cataract Surgery

Introduction

Your child is invited to participate in a research study evaluating a surgical procedure used to treat glaucoma after cataract surgery.

Purpose

To assess the safety and effectiveness of GATT in controlling eye pressure.

Procedures

Your child will undergo surgery and regular follow-up visits including eye examinations and pressure measurements.

Risks

- Bleeding (hyphema)
- Infection (rare)
- Need for additional surgery

Benefits

- Potential reduction in eye pressure
- Decreased need for medications

Confidentiality

All data will remain confidential and anonymized.

Voluntary Participation

Participation is voluntary. You may withdraw at any time.

Consent Statement

I have read and understood the information above and agree to participate.

Guardian Name: _____
Signature: _____
Date: _____