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The effectiveness of gonioscopy-assisted transluminal trabeculotomy (GATT) with polypropylene suture in the treatment of pseudoexfoliative glaucoma

Submission date
09/02/2026

Recruitment status
No longer recruiting

Registration date
13/02/2026

Overall study status
Completed

Last Edited
31/03/2026

Condition category
Eye Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Glaucoma is a longterm eye disease that gradually damages the optic nerve. This happens because the cells that send visual signals from the eye to the brain are lost over time. High pressure inside the eye is one of the main factors that makes the disease worse. The standard glaucoma operation, called trabeculectomy, is known to lower eye pressure well, but it carries a relatively high risk of complications. In recent years, newer procedures called minimally invasive glaucoma surgeries (MIGS) have become much more common because they have fewer risks, allow quicker recovery, and can be done at the same time as cataract surgery. For example, in the United States, the number of MIGS procedures rose sharply between 2012 and 2016 and made up most glaucoma surgeries in 2017.

One MIGS technique is GATT, which uses a fine polypropylene thread to open the eye's natural drainage pathway. It can also be done using a commercial device called the iTrack system, but the polypropylene thread method is inexpensive. In Latvia, MIGS is not widely used because of cost. GATT surgery was introduced in Latvia in November 2020. So far, 120 surgeries have been carried out, and early results suggest it works well for different types of glaucoma, including pseudoexfoliative glaucoma. The procedure has been described in the Latvian Medical Journal, and early results have been presented at professional meetings.

Two publications exist on using GATT with the iTrack catheter for pseudoexfoliative glaucoma, but there is no data on using the polypropylene thread method for advanced glaucoma, and no studies on how GATT affects blood flow in the eye. These blood flow changes can be measured using a scan called OCT angiography.

This study aims to show the longterm effectiveness of GATT with polypropylene thread for treating pseudoexfoliative glaucoma. It will measure success by looking at eye pressure, the amount of medication needed, and complication rates. It also aims to identify risk factors and the effects of other health conditions, and to analyse changes in the eye's microcirculation using OCT angiography.

Who can participate?
Patients aged 18 years and over who require glaucoma surgery due to uncompensated elevated intraocular pressure despite maximum tolerated glaucoma therapy.

What does the study involve?
The study will be conducted as a prospective study at the Riga East University Hospital (RAKUS) ophthalmology clinic “Bikernieki”. The study will be conducted with the approval of the University of Latvia, Life and Medical Sciences Research Ethics Committee and in accordance with the ethical guidelines of the 1975 Helsinki Declaration. A diagnosis of pseudoexfoliative glaucoma will be made by examining the patient with a slit lamp, performing a visual field (VF) test, gonioscopy, intraocular pressure (IOP) and fundus examination. The trial will enrol patients who will provide their written consent to participate in the study. Patients with pseudoexfoliative glaucoma will be divided into two equal groups depending on the severity of the disease, using the depth of the visual field defect mean deviation (MD) as a criterion. Personal data will be pseudonymised, and each patient will be assigned a serial number. All patients will have detailed ophthalmology examinations and will undergo gonioscopy-assisted transluminal trabeculotomy as standalone or combine with cataract surgery. Patients will be follow-up 12 months.

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
The Riga East University Hospital (RAKUS) ophthalmology clinic “Bikernieki”, Latvia.

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

Who is funding the study?
RAKUS, Latvia.

Who is the main contact?
Dr Gunta Udre, udreguntab@gmail.com

Contact information

Type(s)
Scientific, Principal investigator, Public

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Study information

Scientific Title
Efficacy of gonioscopy-assisted transluminal trabeculotomy in different stages of pseudoexfoliative glaucoma: A prospective study

Study objectives
The aim of this study is to prove the long-term effectiveness of gonioscopy-assisted transluminal trabeculotomy (GATT) with polypropylene suture in the treatment of pseudoexfoliative glaucoma, defining the results as a reduction in eye pressure, the amount of medication used, and the number of complications. To identify risk factors and the impact of comorbidities on the outcome of the surgery. To analyse microvascular changes in the optic nerve and retina after surgery using OCT-Angiogram.
Working hypothesis: GATT surgery with polypropylene suture effectively reduces intraocular pressure and the amount of medication used in cases of early, intermediate, and advanced pseudoexfoliative glaucoma 12 months after surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/10/2022, University of Latvia Faculty of Medicine Research Ethics Committee (Jelgavas iela 3, Riga, LV-1004, Latvia; +37167033817; etika.medicina@lu.lv), ref: Nr.71-35/61

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Patients with various stages of pseudoexfoliative glaucoma.

Interventions

Current interventions as of 25/03/2026:

Before minimally invasive glaucoma surgery, all patients undergo a comprehensive ophthalmological examinations, including visual acuity, gonioscopy and measurement of intraocular pressure, dilated fundus examination, retinal nerve fibre layers and ganglionar cells by optical coherence tomography (OCT), radial peripapillary capillaries vessel density, superficial and deep macular vessel density by OCT-Angiography, visual fields detection, pachymetry, endothelial cell count, and the measurement of blood pressure.

Patients will be divided into two equal groups depending on the severity of the disease, using the depth of the visual field (VF) defect mean deviation (MD) as a criterion. The VF was considered valid if the fixation error was less than 20%, false positive <30% and false negative <30%. Personal data will be pseudonymised, and each patient will be assigned a serial number.
Group 1 – initial and moderate glaucoma with visual field defect MD≤12dB
Group 2 – advanced glaucoma with visual field defect MD>12dB

All patients will undergo GATT with polypropylene suture 360° as standalone or on combination with cataract surgery under local anaesthesia. Premedication is prescribed before surgery, Sol. Pilocarpine, Sol. Levofloxacin in the eye to be operated on. Disinfection of the surgical field. Eye speculum. Two paracentesis 1.2 mm, corneal incision 2.2 mm. Sol. Lidocaine 0.3 mm in the anterior chamber, DiscoVisc (Alcon) will be administered. Thermally blunted polypropylene suture 5.0. prepared. Under Jacob-Swan gonioprism control 2 mm goniotomy in the nasal quadrant from 8 till 9 o'clock. Introduction of polypropylene suture into Schlemm's canal using microsurgical forceps and will be guided 360-degree. The end of the thread will be grasped and pulled it out of the anterior chamber. Irrigation – aspiration using bimanual instruments. Determination of venous pulse using the Fellman method. Filling of the anterior chamber with Sol. ProVisc (Alcon). Hydration of wounds. Instillation of Sol. Levofloxacin. Bandage. The course of the operation will be recorded on a data carrier.

After surgery, patients will be prescribed antibiotic and glucocorticoid drops 4 times a day for 14 days, and non-steroidal anti-inflammatory drops for 6 weeks. Pilocarpine drops will be prescribed to all patients after surgery for 4 weeks, depending on the pressure on the following day (if IOP on the first postoperative day was <17 mmHg, then once daily, if <17 mmHg twice daily). Other glaucoma medications were stopped on the first day after surgery. If IOP was elevated, additional glaucoma medications were prescribed, with preference given to carbohydrase inhibitors.

The patients will be followed up for 12 months after the operation.

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Previous interventions:

Before minimally invasive glaucoma surgery, all patients undergo a comprehensive ophthalmological examinations, including visual acuity, gonioscopy and measurement of intraocular pressure, dilated fundus examination, optical coherence tomography (OCT), OCT-Angiography, visual fields detection, pachymetry, endothelial cell count, and the measurement of blood pressure.

Patients will be divided into two equal groups depending on the severity of the disease, using the depth of the visual field (VF) defect mean deviation (MD) as a criterion. The VF was considered valid if the fixation error was less than 20%, false positive <30% and false negative <30%. Personal data will be pseudonymised, and each patient will be assigned a serial number.
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The patients will be followed up for 12 months after the operation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Intraocular pressure measured using a Goldman applanation tonometer at baseline, first day, one week, one month, 3 months, 6 months and 12 months

2. The cumulative surgical success, defined by intraocular pressure, measured using a Goldman applanation tonometry and assessed using Kaplan–Meier estimation with log-rank tests at 12 months

3. Vascular density of optic nerve head and macula measured using optical coherence tomography angiography (OCTA) at baseline, one month, 6 months and 12 months

Key secondary outcome(s)
1. Glaucoma medications measured using data collected from records entering the number of medications at baseline, 1, 3, 6, and 12 months

2. Retinal Nerve Fiber Layer (RNFL) thickness measured using optical coherence tomography at baseline, 1, 6, and 12 months

3. Corneal cell density and pachymetry measured using specular microscope at baseline and 12 months

Completion date
22/10/2025

Eligibility

Key inclusion criteria
1. Patients diagnosed with pseudoexfoliative glaucoma decompensation with maximum tolerated therapy and requiring antiglaucoma surgery
2. Patient has signed the study informed consent form
3. Over 18 years of age
4. Elevated intraocular pressure >20 mmHg in the study eye
5. The optical parts in the study eye is sufficiently clear to perform diagnostic examinations

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Acute inflammation of the anterior or posterior segment of the eye
2. Aphakia
3. Significant dislocation of the intraocular lens
4. Closed-angle glaucoma
5. History of filtration glaucoma surgery, laser trabeculoplasty
6. Patient refuses to participate in the study

Date of first enrolment
02/11/2022

Date of final enrolment
18/09/2023

Locations

Countries of recruitment
Latvia

Study participating centre
Ophthalmology Department, Riga East University Hospital
Lielvardes iela 68
Riga
Latvia
LV-1006

Sponsor information

Organisation
Riga East University Hospital

ROR
https://ror.org/00ss42h10

Funder(s)

Funder type

Funder Name
Riga East University Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/02/2026	No	Yes
Protocol file		04/10/2022	10/02/2026	No	No
Protocol file	version 2	20/03/2026	31/03/2026	No	No