Dear Madam!

Dear Sir!

We invite you to participate in the study "The effectiveness of gonioscopy-assisted transluminal trabeculotomy (GATT) with polypropylene suture in the treatment of pseudoexfoliative glaucoma" conducted by Dr. Gunta Blezura-Udre, Riga East University hospital Ophthalmology Clinic ophthalmologist, University of Latvia doctoral student. The study will be conducted as part of the University of Latvia Doctoral Program, on the basis of which a doctoral thesis will be developed to obtain a Doctor of Medical Sciences degree. We would like to introduce you to the purpose, process, and content of the study. Please read all the information carefully before signing this document! Before signing the document, you have the right to ask questions about the study and receive answers to them.

Aim of the study:

To prove the long-term effectiveness of GATT with polypropylene suture in the treatment of pseudoexfoliative glaucoma. After the operation, regular examinations and non-invasive measurements will be performed to determine whether the disease continues to progress and whether the reduction in eye pressure is sufficient.

Study procedure:

The study will include assessment of best-corrected visual acuity, intraocular pressure, gonioscopy, biomicroscopy, corneal thickness, corneal endothelial cells, visual field, optic nerve and retinal optical coherence tomography (OCT), and OCT angiography for one year in patients with pseudoexfoliative glaucoma. The study will take place from October 24, 2022, to September 20, 2023 for patients who will be admitted to the ophthalmology clinic at Riga East University hospital to undergo gonioscopy-assisted transluminal trabeculotomy (GATT) with polypropylene suture. The course of the operation will be recorded on a data storage device.

All measurements are non-invasive, quick and painless. In order to perform some of the tests, diagnostic drops will be instilled into your eyes, after which your vision may be blurred for a few hours, as well as anaesthetic drops, which will temporarily numb the surface of the eye. All tests will be performed either before the surgery or during the visit, without significantly prolonging the total examination time. Measurements will be taken before the planned surgery and within one year (one week, one month, three months, six months, and one year) after GATT. Patients will be divided into two groups depending on the severity of their disease, but this will not affect the course of treatment or examinations. You will be informed of the results obtained and the progress of the study. All patients will undergo GATT with polypropylene suture. The data obtained will be statistically processed and will be completely encrypted,

without revealing the identity of the patients. Your inclusion in this study will not affect your treatment plan in any way.

Benefits and risks

The aim of the study is to prove the effectiveness of surgery in the treatment of pseudoexfoliative glaucoma. GATT is a minimally invasive surgery which, unlike other minimally invasive surgeries, is low-cost and does not require additional funds to cover the cost of implants. After a successful operation, the patient no longer needs to use glaucoma medication, thus saving money and improving quality of life. Timely glaucoma surgery can halt the progression of the disease and reduce visual impairment in the country. The data obtained will help to understand the risk factors that affect the outcome of the surgery. The examinations performed during the study do not pose any psychological or physical risk. Your treatment plan will not be affected in any way during the study. The additional examinations do not pose any increased risk, so no additional risks to your eye and general health are expected during the study.

The data obtained would make it possible to offer patients the most appropriate method of reducing intraocular pressure in different stages of glaucoma. The results obtained would also be published internationally, improving and deepening glaucoma specialists' understanding of the long-term effectiveness and safety of GATT.

The data will be encrypted in publications. You will be provided with in-depth monitoring of structural changes in the eye over time, ensuring timely pressure control. The study will also ensure long-term reduction of intraocular pressure.

Confidentiality and data security:

Personal data will be processed in accordance with the requirements of the Personal Data Processing Law. The data recorded in the study will be encrypted and entered into a closed system, without including your name, surname, or date of birth. Only the researcher will have access to the data system. The following measurements will be entered into the system: visual acuity, number of glaucoma medication groups used, comorbidities, history of glaucoma surgery, intraocular pressure, corneal pachymetry, corneal endothelium cell analysis, anterior and posterior segment findings in slit lamp biomicroscopy, optic nerve disc excavation ratio, retinal nerve fiber layer thickness, central retinal thickness, macular vascular density and optic nerve measurements, episcleral vein pulse, blood pressure measurements. The data obtained will be statistically processed using data processing software to obtain overall results. If you are interested, you will be informed of the final results of the study and the conclusions reached. If you have any questions or complaints about the processing and storage of your personal data in this study, please contact Dr. Gunta Blezura-Udre, +37129586161, blezura@hotmail.com, who ensures data storage.

Voluntary participation:

Participation in this study is voluntary. You have the right to refuse to participate in the study or to withdraw from the study at any time. Your refusal to participate in the study or withdrawal from the study will not have any adverse effect on the quality of healthcare you receive. We will inform you of any important issues regarding this study that may affect your decision to continue participating in this study.

If you have any questions about this study, please contact Dr. Gunta Blezūua-Udre, Riga East University hospital Ophthalmology Clinic, Lielvardes iela 68, blezura@hotmail.com, +37129586161.

This study has been approved by the LU Life and Medical Sciences Research Ethics Committee: lietvediba@lu.lv

This document has been drawn up in two copies, one of which is kept by the researcher and the other by the research subject.

Consent to participate in the study "The effectiveness of gonioscopy-assisted transluminal trabeculotomy (GATT) with polypropylene suture in the treatment of pseudoexfoliative glaucoma"

I hereby confirm with my signature that:

1) I have read and understood the information about the study contained in this document and understand the nature, purpose, procedure, risks, and benefits of the study;

2) I had the opportunity to ask questions about the study, and my questions have been answered;

3) I understand that my participation in this study is voluntary and that refusal to participate in the study or withdrawal from the study will not result in any adverse consequences;

4) I have been informed about the purpose of personal data processing and the expected scope of data processing;

5) I agree that during this study, my personal data mentioned in the study information will be collected, stored, and processed in accordance with the requirements of regulatory enactments:

6)**I agree to participate in this study.**

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First name, last name Date Signature Researcher:

_____ _____

First name, last name Date Signature Patient