Dear subjects:

You are diagnosed with "primary angle-closure glaucoma" and need surgery. We sincerely invite you to participate in a randomized controlled clinical trial of the efficacy and safety of trabeculectomy versus peripheral iridectomy plus goniotomy in the treatment of advanced primary angle-closure glaucoma. The study will be conducted at Zhongshan Ophthalmic Center (ZOC), Sun Yat-sen University as the principal center, in joint partnership with six other hospitals and eye institutes, including the Handan City Eye Hospital (The Third Hospital of Handan), West China Hospital of Sichuan University, the Second Affiliated Hospital, Harbin Medical University, Shijiazhuang People’s Hospital, the Third Affiliated Hospital of Chongqing Medical University, and the People's Hospital of Chongqing, as the subcenters. The above-mentioned units are all domestic high-level ophthalmic units that can provide professional and adequate medical security for subjects.

This informed consent will provide you with information to help you decide whether to participate in the study. Please read it carefully and talk to the investigator if you have any relevant questions.

Participation in the study is voluntary. The study protocol has been reviewed and approved by the Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-sen University.

1. Why is this study being conducted?

Glaucoma is the first irreversible blinding eye disease in the world. Primary angle closure glaucoma (PACG) is a common and frequently occurring disease in Asia, particularly in China, with high morbidity and blinding rates. The first-line treatment for PACG is surgical treatment, and one of the preferred options for advanced PACG is trabeculectomy, which has been clinically performed for decades and has saved the sight of many patients. With the modernization and iteration of surgical techniques, minimally invasive glaucoma surgery has developed rapidly. Peripheral iridectomy plus goniotomy has achieved good efficacy in the treatment of PACG and is favored by physicians and patients owing to its advantages of less injury, fewer adverse effects and complications, and faster postoperative recovery. Therefore, it is necessary to conduct research in this area to provide a better surgical treatment plan for patients with PACG by comparing the efficacy and safety of traditional surgery and minimally invasive glaucoma surgery.

2. Who is suitable for the study?

- Inclusion criteria
a. Aged 45–80 years,

b. Eyes diagnosed with advanced PACG that meet the following criteria: (1) (2) (3) or (1) (2) (4),

(1) PAS: ≥ 180° range, including nasal and inferior quadrants

(2) IOP > 21 mmHg with or without anti-glaucoma medications, obtained with the Goldmann applanation tonometer

(3) Glaucomatous optic neuropathy (cup-to-disc [C/D] ratio ≥ 0.7, C/D asymmetry > 0.2, or rim width at the superior and inferior temporal areas < 0.1 of the vertical diameter of the optic disc)

(4) Glaucomatous visual field defects (nasal step, arcuate scotoma, and paracentral scotoma on a reliable Humphrey analyzer and a mean deviation of ≤ -12 dB)

c. Transparent crystalline lens and uncorrected visual acuity ≥ 0.63 (Early Treatment Diabetic Retinopathy Study chart), and
d. Axial length of ≥ 20 mm

• Exclusion criteria

a. History of ocular surgery or trauma,

b. Retinal diseases that influence the collection of ocular parameters or other types of glaucoma, including open-angle glaucoma, secondary angle-closure glaucoma, steroideal glaucoma, angle-recession glaucoma, neovascular glaucoma, nanophthalmos, and pseudoexfoliation syndrome,

c. Monophthalmia (best-corrected visual acuity < 0.01 in the non-study eye),

d. An International Standardized Ratio of > 3.0 for patients receiving warfarin or anticoagulant therapy before surgery,

f. Patients with serious systemic diseases, and
g. Pregnant or lactating women

* If both eyes are eligible for the study, the eye with the worse visual field or optic nerve will be included.

3. How is this study conducted?

Recruitment: This is a multicenter study, and the study subjects will be recruited from the general clinic or glaucoma specialist outpatient clinic. Patients make outpatient appointments on the Internet and then complete the screening in the outpatient clinics. If a patient requires surgery for the treatment of PACG, he/she will be automatically approached by the clinical research coordinator to assess compliance with the inclusion and exclusion criteria.
Sample size: This is a multicenter study in China, with 16 patients from the main center and 12 patients from the six subcenters.

Once you have been diagnosed with advanced PACG, we will explain this to you. If you agree to participate in this study, we will collect your information and relevant results as required after you sign the informed consent form.

The study process is as follows:
(1) Informed consent and screening.
(2) The study physician will select the eye for surgery according to the study protocol
(3) Randomization*: Patients will be randomly assigned 1:1 to receive either trabeculectomy or peripheral iridectomy plus goniotomy.
(4) Complete routine pre-operative examinations
(5) Both surgical methods have been used in clinical practice for many years and are performed strictly in accordance with standard surgical techniques.
(6) Postoperative medication and re-examinations will be performed according to the study protocol.
(7) Postoperative follow-up examination constitutes: seven follow-ups and examinations as follows: day 1, day 7, month 1, month 3, month 6, and month 12. With your consent, the follow-up can be extended to 3 years.
(8) Postoperative examination items include visual acuity test, automatic optometry, intraocular pressure using a Goldmann applanation tonometer, gonioscopy, visual field test, fundus photography, optical coherence tomography, ocular bioparameters, and the quality of life questionnaire.
(9) During the study, we will observe changes in your condition at any time and adjust the follow-up plan in time to protect your rights and safety.

* Both surgical methods have been widely used in clinical practice and can effectively reduce the intraocular pressure of patients for years. Therefore, randomization to either group can achieve the treatment goal.
4. What do I need to do to participate in the study?

(1) Understand the study in detail and voluntarily agree to participate.

(2) Accept treatment, review, and follow-up in accordance with the requirements of this study and truthfully inform about the changes in illness.

5. What is the impact of participating in the study on daily life?

(1) You may find these visits and inspections to be inconvenient. In addition, some tests may make you feel uncomfortable. Please consult your study physician if you have any questions regarding the tests and procedures.

(2) Please consult your study physician before using any new prescription or disease-related medications during the study period to avoid conflicts.

(3) For your safety and to ensure the validity of the study results, you are not allowed to participate in any other clinical study.

6. Possible benefits of participating in the study

(1) Subjects participating in this project can use the microhook for free (RMB 4500-6000).

(2) You will be prioritized for screening.
(3) You will receive comprehensive follow-up records with professional advice on glaucoma diagnosis and treatment.

(4) You will receive free postoperative gonioscopic examinations.

(5) You will obtain the privilege of the priority operation arrangement.

The application of the research results may help a vast number of patients with the same disease.

7. Is there any reward for participating in the study?

You will not be paid for your participation in this study, but you will be free to use the Tanito Microhook (RMB 4500-6000).

8. Risks of participating in the study

(1) Trabeculectomy is a conventional surgical method for the treatment of advanced PACG, which has a history of more than 20 years. Goniosynechialysis has been widely used for more than 10 years in the treatment of PACG. As a conventional surgical method for congenital and open-angle glaucoma, goniotomy has been performed in other countries for more than 10 years and has been performed in China for several years. It is characterized by a simple operation, low surgical risk, and few complications (mainly anterior chamber bleeding, which can be absorbed by itself).

(2) The investigator will purchase insurance for the clinical study in accordance with the necessary procedures described in the GCP, and compensation for injuries and damages related to the clinical study will be conducted in accordance with the applicable Chinese laws and regulations.

(3) Possible risks in examination: Risks of examination instruments: All ophthalmic examinations used in this study have been widely used in clinical practice, and the examination itself will not cause adverse effects on the subjects. The Goldmann tonometry examination requires contact with the cornea; however, this risk is minimized by careful operation and strict disinfection by skilled technicians.

9. Is personal information kept confidential?

Yes. Your medical records (private information, test results, etc.) will all be kept at the hospital where you visit. The hospital will record the results of your medical records. Only the researchers, ethics committee members, and drug regulators will be allowed access to your medical records. Your personal identity will not be disclosed in any public report of the results of this study. We will do everything within the law to protect the privacy of your personal medical
information.

10. Is it necessary to participate in the study?

Participation in this study is completely voluntary, and participation is entirely up to you. You may refuse to participate. You can withdraw from the study at any time. If you decide to withdraw from the study, please notify your study physician in advance. If you experience any unusual symptoms at any time during the study period, please inform your study physician or staff.

The study physician may suspend your participation in the study at any time during the study in your best interest for the following reasons: 1. Continuing to participate in this study may be detrimental to you; 2. You need to use the treatment prohibited in this study; 3. You fail to follow the instructions; 4. The study was terminated before its completion.

Alternative treatment: Surgery is the preferred treatment for PACG. Those who do not participate in this study will also need to undergo one of the two surgical options described above.

11. Participation costs

Patients need to pay their own registration fees, pre-operative medication and examination fees, surgery fees, and other routine diagnosis and treatment costs. The study will pay 4500–6000 RMB for TMH in goniotomy as well as postoperative gonioscopy.

12. What to do now?

It is up to you (and your family) to decide whether to participate in the study. Before you decide to participate in the study, ask your doctor as many questions as possible. Thank you for your consideration. If you decide to participate in the study, please let your doctor know and he or she will make all arrangements for you. Please keep this document in mind: Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-sen University (Tel:020-66610729).
Informed Consent · Signature

Statement of Consent:

I have read the above introduction to this study and have had the opportunity to discuss with and ask questions about it from the doctors. All of my questions were answered satisfactorily.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary, and I confirm that I have had sufficient time to consider this and understand that:

- I can always ask my doctor for more information.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights and interests will not be affected.

I am aware that if I drop out of the study, I will be required to inform the doctor of my condition and complete the corresponding physical examination and physical examination, which would benefit the study as a whole.

If I need to take any other medication owing to changes in my condition, I will consult with my doctor in advance or inform my doctor afterwards.

I consent to access to my research materials by the drug regulatory authority, the ethics committee, or the sponsor's representative.

Finally, I agree to participate in the study and promise to follow the doctors’ advice as much as possible.

Signature of subject (or guardian): __ __ __ __ yyyy/mm/dd

Contact Number:

I confirm that the details of the trial, including its rights and possible benefits and risks, have been explained to the patient.

Investigator signature: __ __ __ __ yyyy/mm/dd

Contact number: 020-66618932