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Trabeculectomy versus stepwise treatment for breaking the attack of acute primary angle closure in patients with long attack duration: study design and protocol for a multicentre randomised controlled trial (LAAAC)

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ABSTRACT:

Introduction Acute primary angle closure (APAC) is a common ophthalmic emergency for Chinese patients causing potential visual disabilities. According to current guidelines published by developed countries, a stepwise protocol (medication laser or paracentesis surgery) is recommended for emergency management of APAC. However, patients with APAC in China and developed countries differ in disease characteristics as the Chinese have longer attack duration and lower success rate in breaking the attack with solely medication or laser therapy. It has been proved that long attack duration is a risk factor for failed medical or laser therapies in subsiding APAC. Since prompt and effective treatment is pivotal in preserving visual function as well as avoiding APAC-induced blindness, direct trabeculectomy may largely benefit long-attacking patients with APAC in China.

Purpose The Long-Attacking Acute Angle Closure study aims to compare long-term visual function and safety after different initial treatment strategies: direct surgery (trabeculectomy) or stepwise protocol for patients with APAC with attack duration longer than 72 hours.

Methods and analysis This is a pragmatic, multicentre, randomised controlled trial targeting Chinese patients with APAC duration longer than 72 hours. Eligible participants will be identified at either emergency department or glaucoma clinics, then randomised into stepped treatment group or trabeculectomy group using a computer central randomisation service. The patients will be followed up for 1 year after initial treatment.

Main outcomes and measures The primary outcome is logMAR BCVA 1 year post initial treatment. Secondary outcomes consist of complete success rate in breaking the attack, intraocular pressure value, mean deviation on Humphrey visual field testing and vision-related quality of life collected using the National Eye Institute Visual Function Questionnaire (25 items) 1 year post initial treatment.

Trial registration number ChiCTR2200057289.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Previous studies showed Chinese patients with acute primary angle closure (APAC) had longer attack duration and lower success rate in breaking the attack with solely medication or laser therapy.

WHAT THIS STUDY ADDS

⇒ Since timely abortion of the attack of APAC is crucial for preserving vision function, we hypothesise that direct surgery, compared with stepwise treatment, may largely benefit long-attacking patients with APAC in China.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The multicentre, randomised controlled design with long follow-up enables this study to provide high-level evidence which may help optimise the current APAC treatment pattern, improve the visual outcome and quality of life of Chinese patients with APAC.

INTRODUCTION

Acute primary angle closure (APAC) is a common ophthalmic emergency for Chinese, where intraocular pressure (IOP) rises dramatically (in some cases even over 50 mm Hg).[1] If left untreated, it inevitably leads to glaucomatous optic neuropathy and visual impairment, or even blindness.

Studies have shown that the prevalence of APAC in Chinese descendants significantly outruns any other ethnic groups.[2–4] In mainland China alone, the reported rate of blindness after APAC lies shockingly between 12.54% and 60.77%.[5] Therefore, this blinding emergency causes great concern in China. Our previous work had proposed a critical time window of 4.6 hours for APAC treatment,

within which the blindness rate can be controlled under 1%.[5] Attack duration, being the most modifiable risk factor for APAC-related blindness, is crucial. Thus, effective and prompt treatment is of paramount significance to avert poor visual outcomes as it frees the optic nerve from lethal pressure-induced compression.

According to guidelines published by developed countries, a stepwise protocol (medication laser surgery) is recommended for managing APAC.[1 6] On first visit, patients receive medication as initial treatment. Then the treatment will be escalated to laser if IOP remains uncontrolled. Paracentesis may also be implemented. Surgeries are then warranted once the first two steps fail as initial treatment. When developing the Chinese glaucoma guideline, our scholars took this suggestion into consideration[7] and many glaucoma specialists abide by this protocol during clinical practices. However, there has not yet been any robust evidence-based study conducted to back this protocol, neither is there an interventional evaluation of effect.[8]

Notably, patients with APAC in China and developed countries differ in disease characteristics. To start with, APAC in mainland China experiences remarkably longer attacks. Results from our previous retrospective study found a mean time from symptom to presentation (TST) of 6.49±9.81 days,[5] which is consistent with other studies regarding the Chinese population,[9–12] but evidently longer than what was reported in Western countries (mostly within 24 hours, range 2–72 hours).[13–16] Longer attack duration has been proven to be a risk factor for failed medical or laser therapies.[17 18] Besides, poorly controlled IOP after initial treatment might play a crucial part in the development of chronic glaucoma, long-term visual impairment and blindness.[17 19–21] From our preparatory work (yet to be published), an attack duration of 72 hours distinctively separated satisfying success rate from poor in breaking the attack. Tan *et al* as well found that a mean presentation within 3 days of symptoms was associated with good visual outcome.[20]

Unlike Caucasian subjects with APAC, the effectiveness of medication with or without laser treatment is rather unsatisfying for the Chinese.[22] In light of published research, medication and laser (including laser peripheral iridotomy (LPI) and argon laser peripheral iridoplasty (ALPI)) has an overall success rate of over 70%.[13 17 23] While for the Chinese (Asians), the success rate lies between 50% and 60%,[9 19 20] with nearly half requiring further surgical intervention. In Aung *et al*'s study, approximately 50% of IOP failed to be controlled by medication and laser, with 29.73% (36/111) undergoing trabeculectomy within 1 year.[9] They further argued that early surgical intervention might largely benefit patients with APAC in protecting vision and averting blindness. Though some reported IOP-controlled rate of over 70% in Chinese patients with APAC,[24] heterogeneity exists between this small study sample and the majority of mainland Chinese. In terms of results from our retrospective pilot study, the failure rate of medication in Chinese patients with APAC impended 80%, while the failure rate for ALPI reached beyond 50%.

Stepwise protocol for patients with long APAC duration is time-consuming as waiting medication and laser treatment to take effect before planning surgery can take several days. To seize the treatment window and remedy for vision, a more aggressive approach might be the optimal option, which would allow for a safer precondition for ultimate lens extraction. Moreover, despite some achieving temporary remission, the outcome of laser therapy was not that satisfying, and some also believed that a degree of residual angle closure exists even after treatment.[25 26] Another concerning aspect is that with inadequate initial treatment leading to treatment failure, along with possible poor post-treatment compliance (proven in studies in Hong Kong patients with APAC) resulting in self-terminated follow-up,[27 28] neglect of IOP increase would be inevitable. Consequently, postponed treatment elevation would exacerbate visual impairment. In China, trabeculectomy is a generally recognised and clinically tested mainstay (which is also advised by the Chinese Glaucoma Guideline), even when the eye is still 'hot'.[8] According to published studies regarding angle-closure glaucoma in Asians, though trabeculectomy for APAC eye with mean presenting IOP ranging from 30 to 50 mm Hg has more postoperative complications, it is still safe and effective.[29 30] Complications after trabeculectomy mostly involve shallow anterior chamber (AC), hypotony, choroidal detachment, hyphema, malignant glaucoma and additional surgery. The reported rate of early complications for medically unresponsive angle closure, namely the 'hot' eyes, ranged between 23.9% and 33.3%, with shallow AC being the leading cause. Whereas severe complications such as choroidal detachment did not exceed 5% and malignant glaucoma rarely occurred.[29–32] A substantial amount of researchers are in favour of direct trabeculectomy for APAC as most complications are manageable and can recover with time while benefiting long-term vision preservation. Additionally, the effectiveness of trabeculectomy can be enhanced by cataract surgery combined with goniosynechialysis later when IOP is well-controlled by filtering surgery and phacoemulsification is safe enough. By contrast, some proposed primary lens extraction or primary transscleral cyclophotocoagulation for managing APAC, though lens extraction was mostly studied on medically responsive APAC with controlled IOP,[25 33 34] whereas the IOP-lowering efficacy and long-term outcomes of cyclophotocoagulation alone were not satisfying.[35 36] As far as we know, primary trabeculectomy is rather accessible and practical in clinical settings for the Chinese patients with medically unresponsive APAC.

Herein, we propose that for Chinese patients with APAC duration ≥72 hours direct trabeculectomy could be the initial treatment, which possess the potential of improved efficacy in breaking the attack, minimised duration of high IOP and better long-term visual outcomes. To this end, we present a pragmatic, multicentre,

randomised controlled trial, comparing direct surgical intervention with stepwise protocol in terms of effectiveness in controlling IOP, short-term and long-term visual function, as well as safety. We aim to provide data and high-level evidence on this matter, possibly develop a new treatment protocol that better fits our patients, and in the meantime bring a better quality of life (QoL).

METHODS AND ANALYSIS

Trial design

The Long-Attacking Acute Angle Closure (LAAAC) study is a pragmatic, multicentre, randomised controlled trial, comparing the effectiveness and safety of direct trabeculectomy and stepwise protocol in treating Chinese patients with APAC with symptom duration ≥72 hours. Led by Beijing Tongren Hospital, investigations will be conducted at nine clinical centres in China: Shijiazhuang People's Hospital, Handan Eye Hospital, the Fourth People's Hospital of Shenyang, the Fourth Affiliated Hospital of China Medical University, Fushun Eye Hospital, Anyang Eye Hospital, Hebei Eye Hospital and Shanxi Aier Eye Hospital. Primary outcome will be assessed at 1 year after initial treatment.

Participants and eligibility

Inclusion criteria

1. Conformation of the diagnosis of APAC[5 37–39]: (a) presence of at least two of the following symptoms: ocular or periocular pain, nausea and/or vomiting, an antecedent history of intermittent blurring of vision with halos; (b) presenting IOP of ≥30 mm Hg (measured by non-contact tonometry (NCT), measuring range 0–60 mm Hg); (c) presence of at least one of three of the following signs: conjunctival injection, corneal epithelial oedema and mid-dilated unreactive pupil; and (d) presence of shallow AC with slit-lamp exam (defined as less than 1/4 corneal thickness) in both eyes and a fellow unaffected eye with the presence of 180° or more of iridotrabecular contact with or without peripheral anterior synechia on gonioscopy. When the cornea is oedematous owing to the attack, features of APAC in the fellow eye should be examined first under gonioscopy. Gonioscopy for the affected eye should be done as soon as the cornea restore transparency to the confirmed closed angle.
2. TST≥72 hours.
3. Patients with written informed consent.

Exclusion criteria

1. Secondary angle closure, such as neovascular glaucoma, uveitic glaucoma and glaucoma secondary to trauma or surgeries.
2. Pre-existing blindness (defined according to the WHO criteria as BCVA below 3/60 in the better eye) or history of any diseases that cause severe visual impairment prior to the attack.
3. History of APAC or symptoms indicating a previous attack.
4. Any history of previous intraocular surgery, laser procedure, paracentesis, usage of antiglaucoma medication or topiramate.
5. TST<72 hours.
6. Patients with severe or malignant diseases with life expectancy less than the follow-up period.
7. Patients who plan to move out of the area, thus leading to attrition.
8. Patients participating in other clinical trials.
9. Patients with contraindications of antiglaucoma therapies.

Recruitment procedure

Potential eligible patients will be identified at the first medical visit for APAC at either the emergency department or glaucoma outpatient clinics. Recruitment will be performed by ophthalmologists.

After being assessed for eligibility and informed consent is given, basic medical treatment will start immediately. Those who declined participation will be asked for a reason for refusal. In the meantime, they will be randomised for subsequent treatment accordingly (figure 1). If the first APAC consultation were at the emergency departments, patients will be referred to glaucoma clinic at the latest in time (defined as the baseline visit) at the same centre for further evaluation and start preparation for surgery if applicable. On the other hand, if the first APAC consultation were at the glaucoma clinics, all baseline information would be acquired during this visit.

Interventions

On first medical consultation, medical treatment will be initiated immediately regardless of randomisation. Medical therapies include IOP-lowering eye drops, as well as oral acetazolamide and intravenous mannitol if the presenting IOP exceeds 40 mm Hg. Patients will be monitored for 2–6 hours (based on the clinicians' judgement) to determine the effectiveness of treatment. IOP>21 mm Hg indicates an escalation of treatment. All interventions will be performed following a Standard Operation Procedure (SOP) among centres.

For those who remain unresponsive to medical or laser treatment while awaiting surgery, the performance of paracentesis can be done based on clinicians' judgement.

Stepped treatment

After initial medical treatment, patients with uncontrolled IOP in the stepped treatment group will go on to receive laser therapies (LPI or ALPI depending on the mechanism of angle closure and corneal status). When laser therapy is unavailable, AC paracentesis can be performed instead to temporarily reduce IOP, and then the patients will go on to receive laser treatment as soon as there is access. IOP will be measured at 1 hour, 2 hours and 24 hours after the completion of the procedure. IOP over 21 mm Hg after observation for 24 hours warrants surgery (trabeculectomy). Besides, achieving short-term abortion of the attack yet elevation of IOP>21 mm Hg

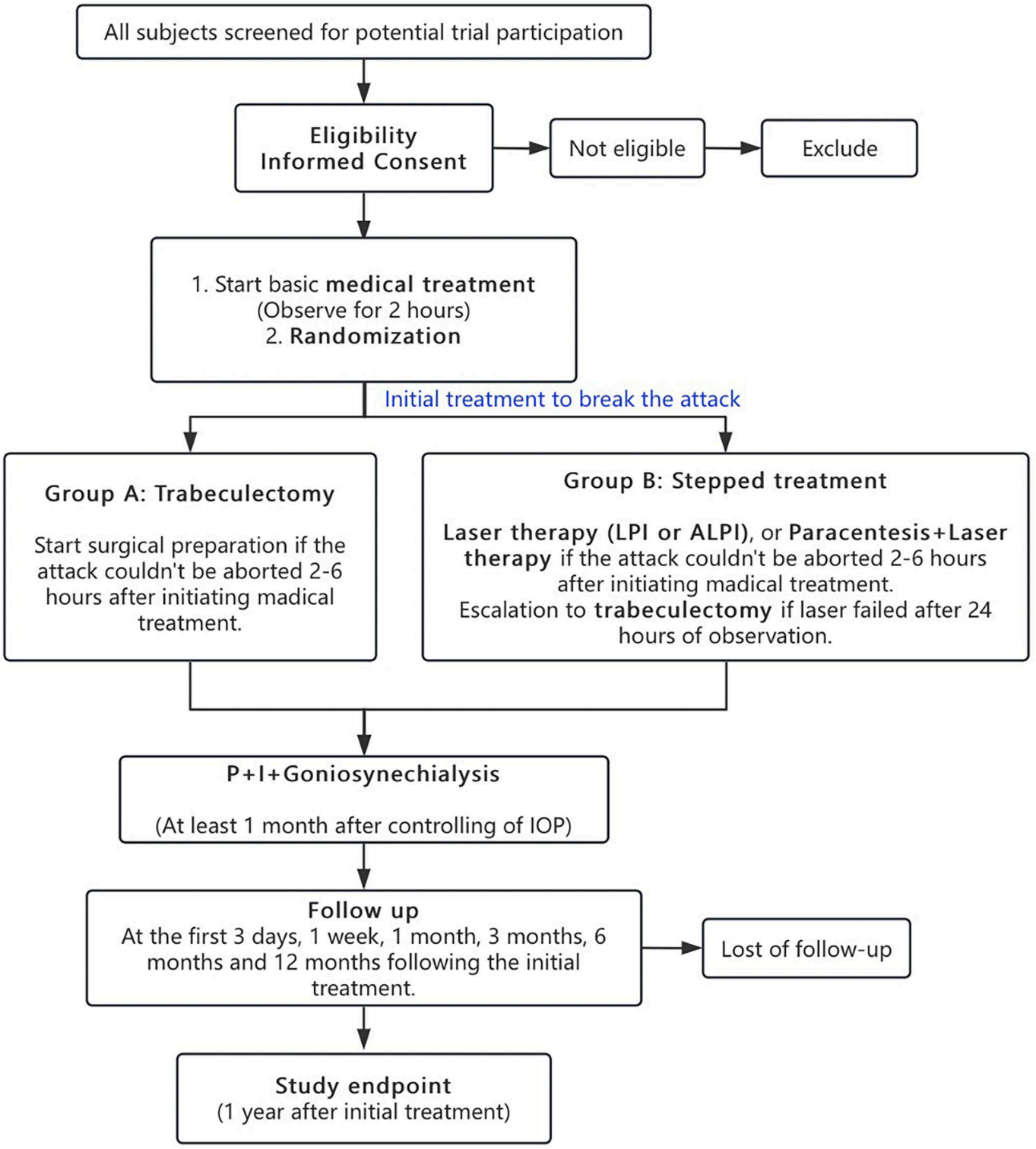

Figure 1 Patient flow. ALPI, argon laser peripheral iridoplasty; IOP, intraocular pressure; LPI, laser peripheral iridotomy.

seen during follow-up visits (with maximum medication) is also an indication for trabeculectomy.

Trabeculectomy

Trabeculectomy will be performed by experienced glaucoma specialists. Preoperatively, levofloxacin eye drops will be administrated. Mitomycin C will be applied under the scleral flap and subconjunctival space for no more than 5 min (judgement based on the patients' age and appearance of Tenon's capsule) during the procedure to augment surgical results as a major reason for the failure of trabeculectomy was found to be bleb fibrosis.[30] Releasable sutures are used for better postoperative

management. Tobramycin dexamethasone in the form of both drops and ointments will be routinely prescribed for 4 weeks as postoperative management. Subconjunctival or periocular injection of dexamethasone would be administered if a patient presents with postoperative hypotony or signs indicating choroidal detachment. For those exhibiting signs highly suggestive of malignant glaucoma, additional cycloplegic drops can be added according to clinicians' judgement.

Subsequent management

During postoperative monitoring, IOP≥21 mm Hg on two consecutive visits warrants additional intervention. This starts with filtration bleb manipulation, including suture lysis, bleb massage, needling or injections of antimetabolites. If bleb management fails to control IOP adequately, antiglaucoma eye drops and oral carbonic anhydrase inhibitors can be added.

Cataract surgery

For all patients with IOP lower than 21 mm Hg after initial treatment, the combination of phacoemulsification, intraocular lens implantation and goniosynechialysis will be performed at least 1 month after the initial treatment of medication, laser or trabeculectomy.

Ethics and dissemination

All participating centres received approval from their respective institutional review board and ethics committee. The study was registered with the Chinese Clinical Trial Registry (ChiCTR2200057289), complied with the Health Insurance Portability and Accountability Act regulations and adhered to the tenets of the Declaration of Helsinki.

Follow-up visits

All eyes will be examined on the first medical visit at each centre, on the day of initial treatment and 1 day, 1 week, 1 month, 3 months, 6 months and 12 months following the initial treatment. The information required at each follow-up visit is demonstrated in online supplemental table 1.

Study endpoints

For those completing a 1-year follow-up, the study reaches its endpoint at 1 year after the initial treatment.

Participants automatically withdraw from the study when:

1. Missing three consecutive follow-ups or more.
2. With poor treatment compliance.
3. Death or suffering from newly diagnosed systemic diseases impeding regular follow-up.

Study endpoint is defined as the last follow-up before withdrawal. However, if any patient violates treatment protocol or lacks essential information which hinders the judgement of efficacy and safety of the trial, they will be excluded from final data analysis.

Outcome measurements and data collection

Outcomes and adverse events will be recorded on a trial-specific case report form. Demographic information, along with medical history of each recruited participant, will be documented at baseline. Extensive ophthalmological examinations of BCVA, IOP and slit-lamp examination will be performed as well if the patients are first presented at the emergency department. Subsequent examination will be completed after referral at glaucoma clinics including gonioscopy, ultrasound biomicroscopy, anterior segment photography, fundus photography, Humphrey visual field (VF), a visual quality questionnaire, optical coherence tomography, specular microscopy and IOL master. Of note, we attach great significance to recording a precise TST (hours), time from presentation to the subsidence of the attack and (if the cornea is oedematous due to the attack) time from symptoms to cornea restoring transparency will also be recorded. During follow-up, we intend to document any related adverse events, poorly controlled IOP needing treatment upgrade and cataract surgeries.

Primary outcomes

The primary outcome of this study is BCVA measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) logMAR E visual acuity (VA) charts[40] 1 year post initial treatment. Notably, resolved attack or controlled IOP do not completely equal good visual outcome, considering that patients' attack duration in different groups may considerably vary due to waiting treatment elevation. Also, since VA most directly reflects one's visual function and concerns patients with glaucoma the most, it would be the most appropriate option for the primary outcome of this study.

ETDRS VA is designed to inspect visual impairment in clinical trials.[40–42] If no letter could be read on the chart, vision of finger count, hand movement, light perception and no light perception will be recorded accordingly. VA examiners are all verified ophthalmologists, have undergone unified training and masked from treatment assignment.

Secondary outcomes

Secondary outcomes consist of complete success rate in breaking the attack, IOP, mean deviation on Humphrey VF testing and vision-related QoL collected from the National Eye Institute Visual Function Questionnaire (25 items) (NEI-VFQ25) 1 year post initial treatment.

Complete success in breaking the attack is defined as IOP<21 mm Hg without the aid of IOP-lowering medication. If IOP can only be controlled with the assistance of medication, the success should be defined as partial rather than complete.

An NCT will be employed for the measurement of IOP, taking several facts into consideration since many patients with APAC are present in an emergency context and that not all centres allow access to Goldmann tonometry.

Box 1 Ancillary information and examinations required

- ⇒ Time from syndrome to presentation, time from presentation to the subsidence of the attack and time from symptoms to cornea restoring transparency.
- ⇒ Number and types of medication needed after laser or surgery.
- ⇒ Further lens extraction surgery or other antiglaucoma surgeries during the follow-up period.
- ⇒ Gonioscopy.
- ⇒ Ultrasound biomicroscopy.
- ⇒ Fundus photography.
- ⇒ Specular microscopy.
- ⇒ Optical coherence tomography.
- ⇒ Other examinations required for the preparation of surgeries.

Three measurements will be taken for each eye by a masked examiner, and the mean values will be used.

VF testing will be performed on Humphrey 24-2 automated perimetry. Reliable VF results are defined as fixation loss<20%, with both positive and negative false <33%.

To further evaluate visual outcomes in patients with APAC, we adopted the NEI-VFQ25 questionnaire, which is a vision-specific health profile measure.[39 43 44] Since the original questionnaire was designed for English speakers, our study adopted the Chinese version, which had been tested for good reliability and validity.[45]

Ancillary measurements

The data presented in Box 1 will also be recorded.

Any ancillary examinations that demand direct contact with the cornea will only be performed when the IOP is maximally controlled and when corneal oedema has resolved so that safety is guaranteed.

Safety and adverse events

We intend to report all serious adverse events, along with complications and unexpected events from each step of intervention. Table 1 illustrates the expected adverse events and complications related to glaucoma care in this trial. If any, all will be extracted, kept detailed records and reported to the Ethics Committee and the Trial Steering Committee in regular progress reports.

Sample size and statistical methods

Sample size has been calculated based on the primary outcome (BCVA) using SAS OnDemand for Academics (SAS Institute, Cary, North Carolina, USA). The power was set at 80% and the significance level was 5%, considering an attrition rate of 10%. In order to detect a minimum difference of 5 ETDRS letters (logMAR=0.1, SD approximately 0.2)[46 47] 1 year after initial treatment, a total of 142 patients (71 per group) is required.

Analysis of outcomes will be performed at the end of the trial on an intention-to-treat basis. After testing for data distribution of normality, demographic information, primary and secondary outcomes will be presented and compared between treatment groups accordingly. Moreover, mixed models will be applied for the investigation of outcomes changes over follow-up time. A cost-effective estimation will also be performed to determine the health economics results of two treatment arms. A p value of <0.05 will be considered statistically significant.

Randomisation and blinding

A remote-automated computer central randomisation service provided by Depa EDC will be used for randomised sequence generation, which guarantees full allocation concealment. Minimisation will be used for treatment allocation to achieve optimal balance between groups.

In this regard, two intervention groups will be balanced simultaneously over five stratification factors: (1) centre, (2) age (<60 years, ≥60 years), (3) IOP at presentation (30–45 mm Hg, ≥45 mm Hg including IOP values that exceed NCT examination threshold), (4) education level (middle school and high school or lower, higher than high school) and (5) TST (72–168 hours, ≥168 hours).

The service can be easily accessed through a WeChat-based mini program. Patients will be assigned randomly (at a 1:1 ratio) following routine medication. Randomisation unit of this trial is the participant rather than the eye.

In light of the nature of surgical intervention, neither the clinical staff nor the participants can be blinded with respect to the intervention. However, outcomes, including BCVA, IOP, VF, NEI-VFQ25 and other ancillary examinations, will be done separately by examiners masked to randomisation.

Table 1 Adverse events and complications

Medication	Allergic/toxic reactions, accommodative spasm, photophobia, discomfort, conjunctival congestion, conjunctival follicles, superficial keratitis, blepharitis, systemic complications, etc
Laser	Intraocular pressure spikes, hyphema, zonular damage, cataract (progression), peripheral anterior synechia progression, corneal burn, laser iris hole occlusion, inflammation, glare, diplopia, etc
Surgery	Hyphema, hypotony, shallow anterior chamber, choroidal detachment, suprachoroidal haemorrhage, choroidal effusion, scaring of filtering bleb, bleb leaks, infection (endophthalmitis/blebitis), decompression retinopathy, macular oedema, corneal oedema, corneal decompensation, etc

Quality control

Researchers participating in this clinical research must be qualified, with professional background and ability to conduct clinical research. All examinations, diagnosis and interventions will be carried out strictly abiding by the SOP. Before the study launches, all centres are visited and convened for training.

The steering committee oversees the whole research and formulates study strategies. The safety and data monitoring committee will monitor safety and other data at six regular intervals during the recruitment phase of the trial. Interim analysis will be conducted 6 months after the initiation of the trial.

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Disclaimer The content of this clinical study is confidential information. Any information about this study, including the study design, methods, results, etc, is within the scope of confidentiality which cannot be discussed with persons outside the study.

Competing interests None declared.

Patient and public involvement Patients will be involved in the conduct of this study by giving informed consent, receiving treatment after randomisation, finishing visual quality questionnaire and coming to regular follow-up.

Patient consent for publication Researchers must obtain signed informed consent to confirm that the subjects fully understand the content of the study and participate voluntarily before the trial starts.

Ethics approval Ethical approval has been obtained from the Ethical Committee of the Beijing Tongren Hospital (TRECKY2021-222) and all subcenters.

Provenance and peer review Not commissioned; internally peer reviewed.

Data availability statement Data are available upon reasonable request.

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