

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of the effect of antiglaucoma drugs with Selective Laser Trabeculoplasty (SLT) in patients with primary open angle glaucoma

#### Protocol summary

##### Study aim

Determining and comparing the effectiveness of drug treatment and Selective Laser Trabeculoplasty (SLT) in patients with POAG referred to AL Zahra Ophthalmology Hospital in 2023

##### Design

Clinical trial with randomized groups on 60 patients. Randomized blocks were used for randomization.

##### Settings and conduct

Al-Zahra Ophthalmology Hospital -2023 The eye pressure of both groups of patients will be evaluated by a doctor before the intervention, 1 month and 6 months after the intervention.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- Age more than 18 years 2- Diagnosis of POAG Criteria for not entering the study: 1- Secondary glaucoma diagnosis 2- One eye patients 3- Having very high IOP (above 30 mm Hg) 4- Patients who have currently received maximum tolerated medical treatment (Maximum Tolerated Medical Treatment), but despite the treatment, their IOP is not controlled. 5- History of laser trabeculoplasty or retinal surgery 6- History of cataract surgery in the last 3 months 7- Active eye infection or inflammation 8- Narrow eye angle 9- Any eye disease that prevents accurate IOP measurement. 10- Pregnant or actively breastfeeding women 11- Any unstable medical condition that prevents compliance with the scientific and ethical bases of the study protocol.

##### Intervention groups

Entered patients will receive one of two treatment groups A or B. 30 patients will receive treatment (Selective Laser Trabeculoplasty 360 degrees in the angle of the eye) and 30 patients will also receive treatment (drug therapy based on the guidelines of the reference books initially with latanoprost drops or second choice with timolol drops).

##### Main outcome variables

Comparison of eye pressure of patients treated with laser

and medicine together 1 month and 6 months after treatment

#### General information

##### Reason for update

##### Acronym

SLT

##### IRCT registration information

IRCT registration number: **IRCT20230330057786N1**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

##### Registration date

2023-09-05, 1402/06/14

##### Registrant information

##### Name

tahereh yavari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3323 3551

##### Email address

taherehyavari71@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of antiglaucoma drugs with Selective Laser Trabeculoplasty (SLT) in patients with primary open angle glaucoma

**Public title**  
Comparison of the effect of laser and medicine in glaucoma

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age more than 18 years Diagnosis of POAG (POAG is an optic neuropathy with increased intraocular pressure in which the angle of the anterior chamber of the eye is open and no secondary disease or cause can be found to justify optic nerve damage or increased intraocular pressure). Newly diagnosed patients and those who are currently receiving the standard first-line treatment, i.e. latanoprost eye drops, but their target IOP has not been achieved.  
**Exclusion criteria:**  
Secondary glaucoma diagnosis One eye patients (patients whose other eye is blind for any reason). Having very high IOP (above 30 mm Hg) Patients who have currently received the maximum tolerated medical treatment (Maximum Tolerated Medical Treatment), but despite the treatment, their IOP has not been controlled. History of laser trabeculoplasty or retina surgery History of cataract surgery in the last 3 months Active eye infection or inflammation Narrow eye angle Pregnant or lactating women Any eye disease that prevents accurate IOP measurement. Like a corneal scar Any unstable medical condition that prevents compliance with the scientific and ethical bases of the study protocol.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The method of random allocation will be using the block method and the use of random blocks. Blocks of four will be used for each intervention group. In this way, a person other than the doctor evaluating the outcome determines the treatment block with the help of random numbers obtained from the computer. Blocks of four will include: TCCT, TCTC, TTCC, CCTT, CTCT, CTTC.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

##### Street address

No. 7, Rajaei st 4, Shahid Rajaei Blvd., Zahedan city

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9819614968

#### Approval date

2023-02-01, 1401/11/12

#### Ethics committee reference number

IR.ZAUMS.REC.1401.392

## Health conditions studied

### 1

#### Description of health condition studied

Primary open angle glaucoma

#### ICD-10 code

H40.1

#### ICD-10 code description

Open-angle glaucoma

## Primary outcomes

### 1

#### Description

Percentage of eye pressure reduction in glaucoma patients

#### Timepoint

At the beginning of the study (before the start of the intervention) and 1 month and 6 months after the start of the treatment

#### Method of measurement

Goldman tonometer

## Secondary outcomes

### 1

#### Description

visual acuity

### **Timepoint**

At the beginning of the study (before the start of the intervention) and 1 month and 6 months after the start of the treatment

### **Method of measurement**

Snellen vision measurement chart

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: The first intervention group: Selective Laser Trabeculoplasty group: a few minutes before the start of Selective Laser Trabeculoplasty, tetracaine drops of 0.5% are poured into the target eye. During the study, all patients in the SLT group underwent laser treatment (Elex SOLO-SLT 2011). It is a Nd:YAG (Q-switched) laser that emits 532 nm radiation with a pulse duration of 3 nanoseconds and a spot size of 400 micrometers and a pulse energy in the range of 0.2 to 1.7 mj. With the patient sitting and the head placed in the slit lamp device, a gonioscope (SLT-Retinal BD10052) is placed on the patient's eye. After that, the laser will be focused on the trabecular meshwork. The entire width of the trabecular mesh with a spot size of 400 µm is irradiated with each pulse. The laser energy will be initially set to 0.8 mj and a laser pulse will be emitted at the 12 o'clock position. If the whitening of the trabecular meshwork does not occur or the cavitation bubble does not appear, the pulse energy will be increased by increasing 0.1 mj until the formation of the bubble. Laser therapy is performed in 360 degrees.

#### **Category**

Treatment - Other

### **2**

#### **Description**

Intervention group 2: Drug therapy group: In the drug therapy group, based on the guidelines provided in the ophthalmology reference books, the first step is to start the treatment with an ophthalmic prostaglandin analog such as latanoprost eye drops (containing 0.005% latanoprost - Sina darou Company). The second step, if the treatment goal is not met during the one-month follow-up, adding a beta-blocker such as timolol eye drops (containing 0.5% timolol maleate - Sina darou Co. with the brand name Optimol) or betaxolol eye drops (containing 0.5% betaxolol hydrochloride - Co. Sina darou will be under the brand name Betaxol). The third step will be brimonidine eye drops (containing 0.2% brimonidine tartrate - Sina darou company under the brand name Brimogan) and the fourth step will be adding dorzolamide eye drops (containing 2% dorzolamide hydrochloride - Sina darou company). Patients will be included in the study who have been newly diagnosed or who have not reached the target IOP determined by the doctor despite regular use of the standard medicine for the first line (latanoprost eye drops). The importance of how to take medicines is explained to the patients, and

the patients are asked to record the side effects of the medicines, such as eye redness, tears, itchy eyes, dry eyes, etc. Patients are advised not to discontinue the drug in case of mild to moderate side effects such as mild redness or itchy eyes. In case of severe side effects such as headache, confusion or worsening of eye pain, contact the treating physician (if the treating physician confirms that the complication is caused by the use of the mentioned drug and continuing to use it for the overall health of the body and health The patient's eye is not suitable, the person is excluded from the study).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra eye hospital

##### **Full name of responsible person**

Tahereh Yavari

##### **Street address**

Shahid Motahari Blvd

##### **City**

Zahedan

##### **Province**

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##### **Web page address**

<https://eye.zaums.ac.ir/>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Zahedan University of Medical Sciences

##### **Full name of responsible person**

Dr. Nur Mohammad Bakhshani

##### **Street address**

2nd Floor, Central Headquarters Building, Zahedan University of Medical Sciences , Dr. Hesabi Square, Gulf of Fars Blvd

##### **City**

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**Email**

zaums.research@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammad Arish

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Tahereh Yavari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

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Alzahra Ophthalmology Hospital, Shahid Mottahari Blvd.

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taherehyavari71@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

No - There is not a plan to make this available