

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Sistan-va-Balouchestan

Postal code

ندارد. اعلام هم شد

Phone

+98 54 3321 9917

Fax

+98 54 3323 3550

Email

taherehyavari71@gmail.com

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

Zahedan

Province

Sistan-va-Balouchestan

Postal code

ندارد

Phone

+98 54 3337 2116

Fax

+98 54 3337 2116

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

Street address

Shahid Motahari Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

کد پستی ندارد...

Phone

+98 54 3322 4991

Email

Arish.Mohammad@gmail.com

Person responsible for scientific 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

Street address

Shahid Motahari Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

کد پستی ندارد...

Phone

+98 54 3322 4991

Email

Arish.Mohammad@gmail.com

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

Street address

Alzahra Ophthalmology Hospital, Shahid Mottahari Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9819614968

Phone

+98 54 3323 3551

Fax

Email

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