

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

comparison of clinical outcomes of phacoemulsification combined with deep sclerectomy versus phacoemulsification combined with trabeculectomy in patients with primary angle closure glaucoma, A randomized controlled clinical trial

Protocol summary

Study aim

To compare IOP reduction and need for medical treatment after surgery between groups and comparing success rate between those groups

Design

This study is a clinical trial in two groups with different surgery, which is blinded on one side and on 60 patients who are classified into two different groups using Excel software and its randomization function. Then the results of the operation will be compared between the two groups

Settings and conduct

The patients will be randomized into two different groups and then each group will undergo a different surgery. The study site is Nikokari Eye Hospital in Tabriz.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. uncontrolled IOP despite maximal tolerable medication 2. controlled glaucoma with multiple eye drops 3. progression of disease in the visual fields exclusion criteria 1. open angle glaucoma 2. secondary angle closure glaucoma: NVG, uveitic glaucoma 3. PACG with 360-degree PAS or having PAS at the site of DS surgery (superior)

Intervention groups

Patients with primary angle-closure glaucoma and significant cataracts

Main outcome variables

1. To compare IOP reduction and need for medical treatment after surgery between groups and comparing success rate between those groups 2. To compare Visual acuity change after surgery between groups 3. To compare Visual field and vertical cup to disc ratio and glaucoma progression after surgery between groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161218031450N7**

Registration date: **2024-02-26, 1402/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-26, 1402/12/07**

Update count: **0**

Registration date

2024-02-26, 1402/12/07

Registrant information

Name

Ali Mostafaie

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-01, 1402/11/12

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of clinical outcomes of phacoemulsification combined with deep sclerectomy versus phacoemulsification combined with trabeculectomy in patients with primary angle closure glaucoma, A randomized controlled clinical trial

Public title

comparison of clinical outcomes of phacoemulsification combined with deep sclerectomy versus phacoemulsification combined with trabeculectomy in patients with primary angle closure glaucoma, A randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Significant cataract with PACG (a closed angle on gonioscopy for at least 180 degrees of angle)
Uncontrolled IOP despite maximal tolerable medication
Controlled glaucoma with multiple eye drops and progression of disease in the visual fields

Exclusion criteria:

Open angle glaucoma
Secondary angle closure glaucoma: NVG, uveitic glaucoma
PACG with 360-degree PAS or having PAS at the site of DS surgery (superior)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Using computer software (Random Allocation Software), the subjects were divided into two intervention groups through four and six blocks with an allocation ratio of 1:1 in two intervention groups (cataract combined with deep sclerectomy) or control (cataract combined with trabeculectomy) are placed. The random sequence of allocation will be produced by a person not involved in the research. And the researcher will not know about the random grouping of patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients will be divided into two groups based on the randomization form. The patient will not know the type of surgery that will be performed. Also, the researcher who collects the data of the study will not know what was done on the patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Abbasi St. in front of police force number 12

City

Tabriz

Province

East Azarbaijan

Postal code

5154645395

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.TBZMED.REC.1402.732

Health conditions studied**1****Description of health condition studied**

Glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

Primary outcomes**1****Description**

Intraocular pressure

Timepoint

The first week, the first month, the third month, the sixth month and the twelfth month after the operation

Method of measurement

Using a slate lamp and a Goldman tonometer

2**Description**

The patient's vision

Timepoint

Months 1, 3, 6, 12 after the operation

Method of measurement

Using the Snellen chart

3

Description

Peripheral visual field

Timepoint

6 and 12 months after the operation

Method of measurement

Using perimeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Deep sclerectomy surgery with cataract. In this group of patients, a surgeon with a glaucoma fellowship undergoes phacoemulsification surgery for the patient's cataract, and deep sclerectomy is performed through scleral incisions in the patient's limbus area and the adjacent conjunctiva to increase the drainage of the aqueous humor.

Category

Treatment - Surgery

2

Description

The second intervention group: combined cataract surgery with trabeculectomy. In this group of patients, a surgeon with a glaucoma fellowship undergoes phacoemulsification surgery for the patient's cataract, and trabeculectomy is performed through incisions in the limbus area of the patient and the adjacent conjunctiva with access to the space of the trabecular meshwork to increase the drainage of the aqueous humor.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikoukari Ophthalmology Hospital

Full name of responsible person

Milad Sheikhan

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistant of Tabriz University of Medical Sciences

Full name of responsible person

Doctor Parviz Shahabi

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Tabriz, Azadi St., Golgasht St., Tabriz University of Medical Sciences, Central Building

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Assistant of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farhad Najafzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All necessary and collected data and information will be provided as data

When the data will become available and for how long

Beginning of the access period from 1404

To whom data/document is available

Professors and colleagues and universities of medical sciences in the field of ophthalmology

Under which criteria data/document could be used

The data will be usable for ophthalmology specialists for use in the ophthalmology clinic and treatment of patients.

From where data/document is obtainable

Tabriz University of Medical Sciences, Department of Ophthalmology

What processes are involved for a request to access data/document

After completing the study, the information will be published in the form of an article.

Comments