Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 comparising success rate between thow 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 comparising success rate between thow 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

Country

Iran (Islamic Republic of)

Phone

+98 41 3655 1332

Email address

mostafaeia@tbzmed.ac.ir

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
Gluocoma

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 Sheikhian
Street address
Abbasi St. in front of police force number 12
City
Tabriz
Province
East Azarbaijan
Postal code
5154545395
Phone
+98 914 574 9251
Email
miladsheikhian007@gmail.com
Web page address
https://www.tbzmed.ac.ir

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
Street address
Tabriz, Azadi St., Golgasht St., Tabriz University of Medical Sciences, Central Building
City
Tabriz
Province
East Azarbaijan
Postal code
5154645395
Phone
+98 41 3657 7336
Email
parvizshahabi@gmail.com
Web page address
https://www.tbzmed.ac.ir
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
Street address

Abbasi St. in front of police force number 12

City
Tabriz

Province
East Azarbaijan

Postal code
5154645395

Phone
+98 41 3657 7336

Email
miladsheikhian007@gmail.com

Web page address
https://www.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Ali Moustafaei

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

Street address
Abbasi St., in front of police force number 12, Nikoukari Ophthalmological Hospital

City
Tabriz

Province
East Azarbaijan

Postal code
5154645395

Phone
+98 41 3657 7336

Email
miladsheikhian007@gmail.com

Web page address
https://www.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Milad Sheikhian

Position
Ophthalmology resident

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

Street address
Tabriz Nikoukari Ophthalmology Hospital

City
Tabriz

Province
East Azarbaijan

Postal code
5154645395

Phone
+98 41 3657 7336

Email
miladsheikhian007@gmail.com

Web page address
https://www.tbzmed.ac.ir

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