

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the Results of Classic and Small Sclerectomy without Graft Methods in Ahmed Glaucoma Valve Insertion: a Randomized Clinical Trial

Protocol summary

Study aim

This single blinded, stratified, randomized clinical trial was designed to evaluate safety and efficacy of Ahmed Glaucoma Valve Insertion with small sclerectomy without graft (SSNG method) in Controlling Post-Operative Elevated Intraocular Pressure

Design

A randomized, single blinded, parallel trial

Settings and conduct

All procedures are performed by unique glaucoma surgeon (M.Yadgari) in Basir eye clinic. data analyzer is blinded in this study.

Participants/Inclusion and exclusion criteria

All Patients with IOPs more than target pressure for which glaucoma drainage implant (GDI) surgery was planned are enrolled in the clinical trial with no age limit. Exclusion criteria are congenital glaucoma, no light perception at baseline, history of ocular surface infection in recent two weeks, pregnancy, breast feeding, lack of healthy conjunctiva for AGV insertion.

Intervention groups

1. Group A included patients undergoing conventional Ahmed Glaucoma Valve (AGV) implantation and after treatment . 2. Group B included patients undergoing Ahmed Glaucoma Valve Insertion with small sclerectomy without graft (SSNG method) .

Main outcome variables

Intraocular pressure (IOP); possible need to anti-glaucoma medications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040928N3**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

Registration date

2021-05-19, 1400/02/29

Registrant information

Name

Maryam Yadgari

Name of organization / entity

Basir eye health research center

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 0404

Email address

sobhanisoheila@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-15, 1400/03/25

Expected recruitment end date

2024-06-14, 1403/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Results of Classic and Small Sclerectomy without Graft Methods in Ahmed Glaucoma Valve Insertion: a Randomized Clinical Trial

Public title

Comparing the Results of Classic and Small Sclerectomy without Graft Methods in Ahmed Glaucoma Valve Insertion: a Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All Patients with IOPs more than target pressure for which glaucoma drainage implant (GDI) surgery is planned are enrolled in the clinical trial with no age limit.

Exclusion criteria:
Congenital glaucoma
No light perception at baseline
History of ocular surface infection in recent two weeks
Pregnancy
Breast feeding
Lack of healthy conjunctiva for AGV insertion

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted Block Randomization will be used. Participants are divided in two parallel groups of intervention (patients undergoing Ahmed Glaucoma Valve Insertion with small sclerectomy without graft) and the control group (the group that receives routine treatment) by using (block size = 4) random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
In the present clinical trial the surgeon and patients will be aware of the classification groups (Intervention and control) and only the biostatistician who analyzed the data are blinded to label assignment of patients to each of 2 arms of the study protocol.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-12-02, 1399/09/12

Ethics committee reference number
IR.IUMS.REC.1399.968

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

First day, first week, month 1 , month 3, 6, 9 and 12 after the surgery

Method of measurement

Goldman applanation tonometry

2

Description

Number of medications

Timepoint

First day, first week, month 1 , month 3, 6, 9 and 12 after the surgery

Method of measurement

Quantitative

Secondary outcomes

1

Description

Best corrected visual acuity (BCVA)

Timepoint

First day, first week, month 1 , month 3, 6, 9 and 12 after the surgery

Method of measurement

Tumbling E-chart

2

Description

Complications

Timepoint

First day, first week, month 1 , month 3, 6, 9 and 12 after the surgery

Method of measurement

Qualitative

Intervention groups

1

Description

Intervention group: included patients undergoing Ahmed Glaucoma Valve Insertion with small sclerectomy without graft (SSNG method) .

Category

Treatment - Surgery

2

Description

Control group: included patients undergoing conventional Ahmed Glaucoma Valve (AGV) implantation and after treatment.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Maryam Yadegari

Street address

Madani Avenue, Tehran.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Basir eye health research center

Full name of responsible person

Ahmad Shojaei Baghini

Street address

4th floor, No 3, Shahid Sheibani Alley, after Keshavarz Blvd, Jamalzadeh Shomali St

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Email

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Web page address

https://behrc.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Basir eye health research center

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Basir eye health research center

Full name of responsible person

Maryam Yadegari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Position

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Results will be shown in terms of published articles.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Basir eye health research center

Full name of responsible person

Maryam Yadegari

Position

Professor

Latest degree

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Other areas of specialty/work