

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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.

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 6694 0404

##### Email

maryam.yadgari@yahoo.ie

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1418643561

##### Phone

+98 21 6694 0404

##### Email

info@behrc.ir

##### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1461783381

##### Phone

+98 21 6694 0404

##### Fax

##### Email

fateme.vafaei86@gmail.com

## Person responsible for scientific 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1461783381

**Phone**

+98 21 6694 0404

**Fax****Email**

fateme.vafaei86@gmail.com

**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**

Specialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1461783381

**Phone**

+98 21 6694 0404

**Fax****Email**

fateme.vafaei86@gmail.com

**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