

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of injection combination of Mitomycin c and Bevacizumab on outcome of intraocular pressure after Ahmed Glaucoma Valve (AGV) implantation surgery

#### Protocol summary

##### Study aim

Evaluation of the effect of simultaneous injection of Bevacizumab and Mitomycin on intraocular pressure after Ahmed glaucoma Valve (AGV) surgery and determination of relative and complete success in each group

##### Design

In this RCT study, 30 eyes of 30 patients in each group are examined. In this study, patients with maximal uncontrollable glaucoma and are candidates for shunt are divided into patients into two groups by block randomization: Patients receiving concomitant AGV with bevacizumab and mitomycin, patients Who do not take medication with AGV.

##### Settings and conduct

After surgery, patients are followed up for one week, four weeks, six weeks, eight weeks, three months and six months. After the operation, in order to evaluate the results of success in the operation, they will be divided into two complete and relative groups. The examiner does not know and will not know about the injectable drug. The single blind method is followed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with maximal uncontrollable glaucoma are candidates for shunting. Exclusion criteria: age under 18 years old; secondary neovascular glaucoma due to tumor or uveitis; follow-up less than 6 months; previous shunt devices; simultaneous injection of bevacizum in vitro IVB; non-diabetic individuals with a history of failed trabeculectomy.

##### Intervention groups

Patients are divided into two groups by randomization block method; patients receiving concomitant administration of bevacizumab and mitomycin with AGV and patients not receiving medication with AGV.

##### Main outcome variables

Intraocular pressure after AGV surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211207053323N1**

Registration date: **2022-10-19, 1401/07/27**

Registration timing: **retrospective**

Last update: **2022-10-19, 1401/07/27**

Update count: **0**

##### Registration date

2022-10-19, 1401/07/27

##### Registrant information

##### Name

Emad Soleimani bayatiani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3291 6555

##### Email address

emadf14@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-16, 1400/09/25

##### Expected recruitment end date

2022-07-31, 1401/05/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of injection combination of Mitomycin c and Bevacizumab on outcome of intraocular pressure after Ahmed Glaucoma Valve (AGV) implantation surgery

## Public title

The effect of injection of Mitomycin c and Bevacizumab on intraocular pressure after Ahmed Glaucoma Valve (AGV) implantation surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patient with uncontrolled glaucoma and indicated for shunt

### Exclusion criteria:

Age below 18 years Neovascular glaucoma secondary to tumor or uveitis Follow up less than 6 months Previous shunt devices Simultaneous intravitreal injection of bevacizumab (IVB) Non-diabetic people with a history of failed trabeculectomy surgery

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Limited Randomization Method We will use block randomization The randomization tool is also used from sequence generation software, which is Random allocation software, random sequence generation software, in addition to simple randomization, is capable of generating random sequence by block method. In order to conceal, we use allocation concealment, which refers to the method used to perform a random sequence on the study participants, so that the allocated group is not known before the allocation of the individual. By using opaque letter envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes), in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the letter envelopes in order They are placed. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The method of blinding or covering a single blind is followed. In this method, the trial is planned in such a

way that the participant does not know which of the two control or test groups she belongs to.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahwaz University of Medical Sciences

##### Street address

Ethics Committee of Ahwaz University of Medical Sciences

##### City

Ahwaz

##### Province

Khouzestan

##### Postal code

6155844419

#### Approval date

2021-08-06, 1400/05/15

#### Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.082

## Health conditions studied

### 1

#### Description of health condition studied

Neovascular glaucoma

#### ICD-10 code

H40.10X0

#### ICD-10 code description

Unspecified open-angle glaucoma, stage unspecified

## Primary outcomes

### 1

#### Description

Intraocular pressure reduction percentage after surgery

#### Timepoint

One week, four weeks, six weeks, eight weeks, three months and 6 months are followed

#### Method of measurement

Applanation tonometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: to insert the AGV (scleral patch graft, scleral tunnel), the conjunctiva is cut 4 mm away from the limbus in the upper outer quadrant. 20 mg of triamcinolone is injected under the tendon around it and fixed to the sclera with 2 sutures with 0-0 silk thread. The AGV tube enters the anterior chamber from 2 mm of the limbus, so that 1-2 mm of it is inside the anterior chamber. The tube is then sutured to the sclera with 0-10 nylon thread. In the SPG method, the donor sclera is placed approximately 7 x 4 mm on the exposed part of the tube and then it is attached to the sclera with 0-10 nylon. Create a small tunnel with a 23 gauge needle, through which the tube enters the anterior chamber and the two sides of the flap are sealed with nylon 0-10. Finally, the conjunctiva and tendon are sutured continuously with 10-10 and vicryl thread. Mitomycin is placed in the form of a sponge with a concentration of 0.04% for 2 minutes under the conjunctiva. 0.025ml is injected intrachemically with a 23-gauge needle head.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: to insert the AGV (scleral patch graft, scleral tunnel), the conjunctiva is cut 4 mm away from the limbus in the upper outer quadrant. 20 mg of triamcinolone is injected under the tendon around it and fixed to the sclera with 2 sutures with 0-0 silk thread. The AGV tube enters the anterior chamber from 2 mm of the limbus, so that 1-2 mm of it is inside the anterior chamber. The tube is then sutured to the sclera with 0-10 nylon thread. In the SPG method, the donor sclera is placed approximately 7 x 4 mm on the exposed part of the tube and then it is attached to the sclera with 0-10 nylon. Create a small tunnel with a 23 gauge needle, through which the tube enters the anterior chamber and the two sides of the flap are sealed with nylon 0-10. Finally, the conjunctiva and tendon are sutured continuously with 10-10 and vicryl thread.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital

##### Full name of responsible person

Emad Soleimani Bayatiani

##### Street address

Twenty-four meter street of Imam Khomeini Hospital

##### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6155844419

#### Phone

+98 21 2245 4292

#### Email

emadf14@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Ms. Maryam Reisian

##### Street address

University City - Ahvaz Jundishapur University of Medical Sciences, Ground Floor, Room 4

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

613571579445

##### Phone

+98 61 3311 3817

##### Email

research@ajums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Emad Soleimani Bayatiani

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Education

**Street address**

Imam Khomeini Hospital, 24 meters Street,  
Ophtalmology department

**City**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Emad Soleimani Bayatiani

**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Emad Soleimani Bayatiani

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**Email**

emadf14@yahoo.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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable