

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Ahvaz

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

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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

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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

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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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