Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparision of the effect of subconjunctival injection of Bevacizumab and Mitomycin in outcome of Ahmed Glaucoma Valve (AGV) implantation

Protocol summary

Study aim

Comparison of the effect of sub-conjunctival Bevacizumab and Mitomycin on intra-ocular pressure after Ahmed glaucoma Valve (AGV) implantation and determination of complete and relative success in each group

Design

Double blind clinical trial with parallel groups, phase 3 on 54 patients

Settings and conduct

In this study, which will be performed in Rasool Akram Hospital, 29 eyes of 29 patients in each group are entered. Patients with uncontrolled glaucoma with full medications or intolerant to medications who candidates for shunt will enter the study. Patients will divide into two groups by block randomization: half of them will receive sub-conjunctival bevacizumab and the other half Mitomycin . This is a randomized double-blind study in which neither the patients nor examiner are informed of the drug groups.

Participants/Inclusion and exclusion criteria

Uncontrollable glaucoma patients with full medications who are candidated for shunt implantation will enter the study. Patients will be excluded from the study by the following criteria: • Age under 18 years • Secondary neovascular glaucoma due to tumor or uveitis • Follow-up less than 6 months • Previous shunt devices pregnant patients

Intervention groups

Patients will be randomly divided into two categories: patients with AGV that receive subconjunctival bevacizumab injection at the end of surgery adjacent to plate, and patients who receive sub-conjunctival mytomicin .

Main outcome variables

Duration of glaucoma Past medical history Past surgical history Bevcizumab or Mitomycin C injected during surgery Type of glaucoma Preoperative intraocular pressure, one day, one week, one month, three months and 6 months after surgery Number of preoperative drugs Number of drugs after surgery (last follow-up) Complications of surgery in two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210521051355N1**
Registration date: **2021-09-28, 1400/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-28, 1400/07/06**
Update count: **0**

Registration date

2021-09-28, 1400/07/06

Registrant information

Name

Kiandokht Ghamari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 6185

Email address

kian2_gh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-08, 1400/06/17

Expected recruitment end date

2024-09-07, 1403/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effect of subconjunctival injection of Bevacizumab and Mitomycin in outcome of Ahmed Glaucoma Valve (AGV) implantation

Public title

Comparision of the effect of subconjunctival injection of Bevacizumab and Mitomycin in outcome of Ahmed Glaucoma Valve (AGV)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Uncontrolled glaucoma with full medications First shunt candidate patients

Exclusion criteria:

Under 18 years old patients Secondary neovascular glaucoma due to tumor or uveitis Under 6 month follow up Previous shunts pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization is performed to make the number of patients one at last. In this way, the four blocks will be determined as permutations A and B. To reach the sample size 29 people in each group need to run 7 blocks. Finally, the last two will be randomly assigned to two groups. There are generally six possible permutations for sequences A and B. Write all possible sequences and assign them the numbers 1 to 6. Then we randomly (randomly) select one of the possible sequences each time. Sampling of these 6 sequences may be done by placement so that it is not possible to predict the next selected sequences. Permutations: 1, A A B B 2, A B A B 3, A B B A 4, B B A A 5, B A B A 6, B A A B

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blind study, in which patients and the examiner don't know about the type of the drug used for sub-conjunctival injection.Only the main researcher is aware of type of medications. This procedure is utilized to prevent bias in research results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University of Medical sciences

Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-06-29, 1400/04/08

Ethics committee reference number

IR.IUMS.REC.1400.314

Health conditions studied

1

Description of health condition studied

uncontrolled glaucoma

ICD-10 code

H40.50X3

ICD-10 code description

Glaucoma secondary to other eye disorders, unspecified eye, severe stage

Primary outcomes

1

Description

IOP changes after Ahmed valve implantation with sub-conjunctival injection of bevacizumab or mitomycin

Timepoint

IOP measurement before surgery, 1, 7, 30 days and 3, at least 6 month after surgery and in the last follow up after surgery

Method of measurement

Goldman tonometer

Secondary outcomes

1

Description

number of glaucoma medication after surgery

Timepoint
Baseline,first day,one week,first month,three months,6 months and last follow up
Method of measurement
counting the number of antiglaucoma drugs

2

Description
complications in each group
Timepoint
first day,First week,first month,three months,6months after surgery
Method of measurement
qualitative and descriptive

Intervention groups

1

Description
To insert the Ahmed Glaucoma Valve (AGV),peritomy will performed by conjunctival incision at 4 mm from the limbus in the superotemporal quadrant. Ahmed valve will prime with balanced salt solution and fix with 8-0 nylon into sclera. Ahmed valve tube will insert from 2 mm of the limbus into anterior chamber.The tube is then sutured to the sclera with 10-0 nylon suture. An scleral patch graft by 10-0 nylon on the tube and conjunctiva and tenon will suture continuously with 8-0 vicryl suture. Patients will randomly receive subconjunctival injection of 0.1 ml of Bevacizumab (25 mg/ml) from Behestan Darou or 0.1ml of Mitomycin %0.2mg from Kyowa Japan company adjacent to Ahmed valve plate.
Category
Treatment - Drugs

2

Description
Control To insert the Ahmed Glaucoma Valve (AGV),peritomy will performed by conjunctival incision at 4 mm from the limbus in the superotemporal quadrant. Ahmed valve will prime with balanced salt solution and fix with 8-0 nylon into sclera. Ahmed valve tube will insert from 2 mm of the limbus into anterior chamber.The tube is then sutured to the sclera with 10-0 nylon suture. An scleral patch graft by 10-0 nylon on the tube and conjunctiva and tenon will suture continuously with 8-0 vicryl suture. Patients will randomly receive subconjunctival injection of 0.1 ml of Mitomycin %0.2mg from Kyowa Japan company adjacent to Ahmed valve plate.:
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Dr.Arezoo Miraftabi
Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, 1449614535, IRAN
City
Tehran
Province
Tehran
Postal code
14665-354
Phone
+98 21 6650 9162
Email
kian2_gh@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Professor Masood Naseripour
Street address
Iran University of Medical Sciences Shahid Hemmat Highway Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6650 9162
Email
adminsite@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr.Arezoo Miraftabi

Position

Associated professor of ophthalmology

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6435 1000

Email

Kian2_gh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Arezoo Miraftabi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, Iran

City

Toronto

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6650 9162

Email

miraftabia@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Kiandokht Ghamari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran, 1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

14665-354

Phone

+98 21 6435 1000

Email

kian2_gh@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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available