

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation of the effect of subconjunctival 5-fluorouracil on the outcome of Ahmed valve in neovascular glaucoma: Randomized Clinical Trial

Protocol summary

Study aim

Comparison of success rate of AGV surgery with and without Adjunctive 5-fluorouracil treatment in patients with neovascular glaucoma

Design

Clinical trial study with two parallel groups, randomized using computer permuted block randomization, 35 patients in each group are included and followed up for at least 6 months.

Settings and conduct

This study will be performed on patients with neovascular glaucoma requiring shunt surgery who are referred to the glaucoma clinic of Rasoul Akram Hospital. Patients after randomization are divided into two groups. In the shunt surgery group alone, Ahmed shunt implanted in the superotemporal area at a distance of 10 mm from the limbus. In the shunt surgery with 5FU injection group, In addition to the shunt implantation in the previous method, 5FU is injected in the first, third and fifth weeks of follow-up. Patients are then examined regularly to evaluate the success and complications of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with neovascular glaucoma who require implant Ahmed shunt to control ocular pressure. Exclusion criteria: No Light Perception patients, age less than 18 years, history of any type of eye surgery including previous glaucoma and retinal surgeries (except uncomplicated cataract surgery), history of cyclodestructive procedures, pregnant patients.

Intervention groups

Patients with neovascular glaucoma are divided into two groups. In one group, patients underwent Ahmed shunt surgery and in the other group, patients underwent Ahmed shunt surgery with 5FU injection.

Main outcome variables

Success rate, incidence of hypertensive phase, complications, intraocular pressure before and after

surgery, number of medication used before and after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052357N2**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Farhad Najafzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 5106

Email address

najafzadeh.farhad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-26, 1400/11/06

Expected recruitment end date

2023-01-26, 1401/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of subconjunctival 5-fluorouracil on the outcome of Ahmed valve in neovascular glaucoma: Randomized Clinical Trial

Public title

Subconjunctival 5-fluorouracil on the outcome of Ahmed valve in neovascular glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with neovascular glaucoma Lack of eye pressure control with medication

Exclusion criteria:

Patients with other types of glaucoma

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we will use the random block method so that the number of samples in the two groups is the same. The blocks are considered as 4, with a and b representing the two study groups. All possible permutations for a block of 4 are as follows: aabb, abba, abab, bbaa, baab, baba. From these 6 permutations, one block will be selected at a simple random time. The reason for this is to reduce the likelihood that final allocations will be predictable. After selecting the block, the person will be assigned to group a or b in the same way.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Rasoul Akram Hospital, Maziar Mansouri St., Sattar Khan St.

City

Tehran

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Postal code

14456131310

Approval date

2022-01-25, 1400/11/05

Ethics committee reference number

IR.IUMS.REC.1400.1009

Health conditions studied**1****Description of health condition studied**

neovascular glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

Primary outcomes**1****Description**

Intraocular pressure (IOP)

Timepoint

Before surgery, first day, first week, third week, fifth week, third month, sixth month after surgery

Method of measurement

Intraocular pressure is measured with a Goldmann Applanation Tonometer (GAT).

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients with neovascular glaucoma undergoing shunt implant surgery with during surgery. This method will use Ahmad FP7 model valved shunt (New World Medical, LA), which is one of the most commonly used shunts in the world. First, Mitomycin C at a dose of 0.04% is placed in the shunt plate for two minutes and then rinsed. The shunt is fixed and then the shunt tube is inserted into the eye and fixed with nylon 10.0 thread. The conjunctiva is also swabbed with 8.0 vicryl sutures. After the operation, patients undergo regular examinations according to a specific protocol to evaluate the effectiveness as well as possible complications.

Category

Treatment - Surgery

2**Description**

Intervention group: Patients with neovascular glaucoma undergoing shunt implant surgery with 5FU during and after surgery. This method will use Ahmad FP7 model valved shunt (New World Medical, LA), which is one of the most commonly used shunts in the world. First, Mitomycin C at a dose of 0.04% is placed in the shunt plate for two minutes and then rinsed. The shunt is fixed and then the shunt tube is inserted into the eye and fixed with nylon 10.0 thread. The conjunctiva is also swabbed with 8.0 vicryl sutures. After the operation, patients undergo regular examinations according to a specific protocol to evaluate the effectiveness as well as possible complications. Also in the first, third and fifth weeks, 5FU injections are given as a subconjuncta with a volume of 0.1 ml containing 5 mg of the drug.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Glaucoma clinic of Rasoul Akram Hospital in Tehran

Full name of responsible person

Farhad Najafzadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Abbas Motavallian

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Iran University of Medical Sciences, Hemmat Highway

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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

Farhad Najafzadeh

Position

Glaucoma Fellowship Assistant

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Arezoo Mirafzabi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farhad Najafzadeh

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology