# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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**

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**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
**Province**
Tehran
**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 surgeryl
**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 subconjugate 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
**Street address**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**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**
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Arezoo Miraftabi

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Subspecialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Non-faculty specialist physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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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