

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation the Efficacy of Ahmed Glaucoma Valve Implantation with and with out Mitomycin C(MMC) during surgery in patients with glaucoma

Protocol summary

Summary

This single-center randomized controlled double-blind clinical trial study was designed to evaluate the efficacy of Mitomycin C (MMC) in Ahmed Glaucoma Valve(AGV) implantation. All patients older than 18 years old with uncontrolled glaucoma requiring glaucoma drainage device implantation are eligible for the study while patients younger than 18 years old ; the ones with active iris neovascularization: anterior staphyloma: Breast-feeding and pregnant women: patients with history of shunt surgery: corneal lesions which prevents IOP measurements with Goldan Tonometer were all excluded. A total number of 30 patients in the case group and 30 patients in the control group finally enrolled in the trial. The intervention could be done during surgery when after peritomy, the cotton soakedapplicator with 0.02% MMC or balanced salt solution (BSS) is placed in subtenon area for 2 minutes followed by washing the area with large amounts of serum and the implantation of Ahmed Glaucoma Valve. The IOP measurement would be the primary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101024459N1**

Registration date: **2016-01-14, 1394/10/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-14, 1394/10/24

Registrant information

Name

Afsaneh Malekpoor

Name of organization / entity

Tehran | University of Medical Sciences -Farabi Eye Hospital

Country

Iran (Islamic Republic of)

Phone

+98 215540000314

Email address

a-malekpoor@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Efficacy of Ahmed Glaucoma Valve Implantation with and with out Mitomycin C(MMC) during surgery in patients with glaucoma

Public title

Effect of mitomycin C in glaucoma shunt surgery

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:Uncontrolled glaucoma patients under 18 years that are candidates for shunt surgery exclusion criteria:Patients under 18 years; active iris neovascularization; anterior staphyloma; Breast-feeding and pregnancy; Previous shunt surgery; corneal lesions Which prevents IOP measurement

Age

From 17 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blvd, Tehran

City

Tehran

Postal code**Approval date**

2015-06-22, 1394/04/01

Ethics committee reference number

IR.TUMS.REC.1394.214

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

glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

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

intra oclar pressure

Timepoint

before intervention and one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

goldmann tonometer

Secondary outcomes**1****Description**

Tube-corneal contact

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

slit lamp exam

2**Description**

The number of drugs used to control intra ocular pressure

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

history

3**Description**

Hyphema

Timepoint

one day and one week and one month and 3 months after intervention

Method of measurement

slit lamp exam

4**Description**

Retraction of tube from anterior chamber

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

slit lamp exam

5**Description**

Tube/implant exposure

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

slit lamp exam

6**Description**

Flat chamber/transient hypotony

Timepoint

one day and one week after intervention

Method of measurement

goldmann tonometer

7

Description

Choroidal effusion

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

ocular ultrasonography

8

Description

Blocked tube

Timepoint

one day and one week and one month and 3 months and 6 months and 12 months after intervention

Method of measurement

slit lamp exam

Intervention groups

1

Description

After informing the patients about the procedure, and signing a consent form, the patients were randomly divided in two groups to receive intra-operative MMC or a Placebo. The surgical procedure consisted of a 1-stage Ahmed Glaucoma Valve implantation using a standardized surgical technique for all patients. After administration of topical anesthesia (in both groups), a fornix or limbal based conjunctival flap was applied in the superotemporal quadrant. For the control group, a cotton applicator soaked in a balanced salt solution (BSS) was placed on the Episclera, under the conjunctiva and Tenon's capsule for a contact time of 2 minutes, at the site where the implant plate was to be placed, followed by irrigation with 30 ml of BSS. Then the tube was positioned in the anterior chamber or the sulcus. A donor sclera or a corneal lenticule was fashioned from banked tissue and secured with interrupted 8-0 vicryl sutures over the exposed portion of the tube.

Category

Treatment - Drugs

2

Description

After informing the patients about the procedure, and signing a consent form, the patients were randomly divided in two groups to receive intra-operative MMC or a Placebo. The surgical procedure consisted of a 1-stage Ahmed Glaucoma Valve implantation using a standardized surgical technique for all patients. After administration of topical anesthesia (in both groups), a fornix or limbal based conjunctival flap was applied in the

superotemporal quadrant. For the intervention group, a cotton applicator soaked in a balanced salt solution (BSS) was placed on the Episclera, under the conjunctiva and Tenon's capsule for a contact time of 2 minutes, at the site where the implant plate was to be placed, followed by irrigation with 30 ml of BSS. Then the tube was positioned in the anterior chamber or the sulcus. A donor sclera or a corneal lenticule was fashioned from banked tissue and secured with interrupted 8-0 vicryl sutures over the exposed portion of the tube.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Doctor Ghasem Fakhraee

Street address

No.13366, Farabi eye Hospital, Qazvin square, South Kargar Avenue, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Farabi Eye Hospital

Full name of responsible person

Doctor Afsaneh Malekpoor

Street address

No. 13366, Farab eye Hospital, Qazvin square, South Kargar Avenue, Tehraan

City

Tehraan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Farabi Eye Hospital

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Farabi Eye Hospital

Full name of responsible person

Doctor Ghasem Fakhraee

Position

Associate Professor

Other areas of specialty/work**Street address**

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Contact

Name of organization / entity

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Full name of responsible person

Doctor Ghasem Fakhraee

Position

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Person responsible for updating data

Contact

Name of organization / entity

Farabi Eye Hospital

Full name of responsible person

Doctor Ghasem Fakhraee

Position

Associate Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty