

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of subconjunctival Bevacizumab in Ahmed Glaucoma Valve Surgery”

Protocol summary

Summary

This prospective randomized clinical trial was designed to evaluate efficacy and safety of subconjunctival bevacizumab injection during Ahmed glaucoma valve surgery. The inclusion criteria were inadequately controlled glaucoma patients who were candidate for AGV insertion with at least 6 months of postoperative follow-up. The exclusion criteria were age younger than 18 years or being pregnant or currently breast feeding. Patients with corneal problem with unreliable IOP measurements or previous Ahmed valve surgery or scleral buckling were excluded from the study. Patients were selected randomly in conventional Ahmed glaucoma valve surgery (group 1) or Ahmed glaucoma valve surgery with 2.5 mg sub-conjunctival bevacizumab injection (group 2). A total number of 25 patients in group 1 and 25 patients in group 2 finally enrolled in the study. Bevacizumab was injected adjacent to Ahmed valve in study group in the end of surgery. The primary outcome measures were change in IOP and surgical success: post-operative IOP \leq 21 mm Hg with at least 20% reduction in IOP, either with no medication (complete success) or with no more than 2 medications (qualified success). The second outcome measure was surgical complications in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042527595N1**

Registration date: **2016-08-03, 1395/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-03, 1395/05/13

Registrant information

Name

Arezoo Miraftabi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 8811

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University Of Medical Sciences

Expected recruitment start date

2014-04-30, 1393/02/10

Expected recruitment end date

2015-10-02, 1394/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of subconjunctival Bevacizumab in Ahmed Glaucoma Valve Surgery”

Public title

Effects of Bevacizumab in Ahmed Glaucoma Valve Surgery”

Purpose

Treatment

Inclusion/Exclusion criteria

In this randomized clinical trial inclusion criteria are:1- age more than 18 with IOP>21 mmHg with maximal medications ;2- intolerance to medications ;3-history of previous cataract surgery or trabeculectomy with

uncontrolled IOP ;4-low success of trabeculectomy due to conjunctival scar .Exclusion criteria are :1-patients with VA NLP; 2-undesirable informed consent ;3-patients who can not be present for follow up; 4-history of previous shunt surgery or CPC; 5-History of SB or Silicone in the eye ;6-Vitreous in AC which need VitX ;7-uveitis ;8-nanophthalmous; 9-struge weber or any disease with increased episcleral pressure ; 10-patients who need adjunct surgery in addition to shunt ;11 -NVG 12-pregnancy or lactating patients will be enrolled from Radoul Akram Hospital and Central eye clinic and the procedure will be done with same techniques by Dr.Miraftabi and Nilforoushan.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemmat Highway

City

TEHRAN

Postal code

Approval date

2014-01-01, 1392/10/11

Ethics committee reference number

92031223317

Health conditions studied

1

Description of health condition studied

glaucoma

ICD-10 code

H40

ICD-10 code description

GLAUCOMA

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Before surgery,1 day ,one week,One month,Three months,6 months and every three month after 6 months

Method of measurement

Goldman applanation tonometry

Secondary outcomes

1

Description

Number of glaucoma medications

Timepoint

Before surgery,1 day ,one week,One month,Three months,6 months and every three month after 6 months

Method of measurement

quantitative

2

Description

postoperative complications

Timepoint

Before surgery,1 day ,one week,One month,Three months,6 months and every three month after 6 months

Method of measurement

qualitative

Intervention groups

1

Description

Insertion of Ahmed valve in supra temporal area of eye and no injection of bevacizumab in the end of surgery

Category

Treatment - Drugs

2

Description

Insertion of Ahmed valve in supra temporal area of eye and injection of 2.5mg bevacizumab in subconjunctiva adjacent to Ahmed valve in the end of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Arezoo Miraftabi

Street address**City**

TEHRAN

2

Recruitment center

Name of recruitment center

Central eye clinic

Full name of responsible person

Navid Nilforoushan MD

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University Of Medical Sciences

Full name of responsible person

Seyed Ali Javad Mousavi

Street address

Hemat highway

City

Tehran

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

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

Iran University of Medical Sciences

Full name of responsible person

Arezoo Miraftabi MD

Position

Assistant professor

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

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Person responsible for scientific inquiries

Contact

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Glaucoma fellowship

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

resident of ophthalmology

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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