

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Pretreatment with topical betamethasone in ahmed glaucoma valve implantation

Protocol summary

Study aim

This double blinded, stratified, randomized clinical trial was designed to evaluate safety and efficacy of pre-treatment with Betamethasone eye drop in Ahmed Glaucoma Valve implantation

Design

A randomized, double blinded, parallel trial

Settings and conduct

All procedures were performed by unique glaucoma surgeon (M.Yadgari) in Basir eye clinic. Participants and data analyzer were blinded in this study.

Participants/Inclusion and exclusion criteria

Patients with no age limit with IOPs less than target pressure in whom Glaucoma Drainage Implant (GDI) surgery was planned were enrolled in the study. Exclusion criteria were no light perception at baseline or history of ocular surface infection in recent two weeks, pregnancy, breast feeding, lack of healthy conjunctiva for AGV insertion, and sensitivity to Betamethasone eye drop.

Intervention groups

1) Insertion of Ahmed valve in supratemporal quadrant with prescribed betamethasone eye drop 1% from 3 days before surgery until the time of surgery 2) Insertion of Ahmed valve in supratemporal quadrant with no prescription of betamethasone before surgery

Main outcome variables

Intraocular pressure (IOP); possible need to anti-glaucoma medications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180902040928N1**

Registration date: **2019-01-05, 1397/10/15**

Registration timing: **retrospective**

Last update: **2019-01-05, 1397/10/15**

Update count: **0**

Registration date

2019-01-05, 1397/10/15

Registrant information

Name

Maryam Yadgari

Name of organization / entity

Basir eye health research center

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 0404

Email address

sobhanisoheila@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pretreatment with topical betamethasone in ahmed glaucoma valve implantation

Public title

Pretreatment with topical betamethasone in ahmed glaucoma valve implantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with no age limit with IOPs less than target pressure in whom glaucoma drainage implant (GDI) surgery was planned were enrolled in the study

Exclusion criteria:

Exclusion criteria were no light perception at baseline history of ocular surface infection in recent two weeks pregnancy breast feeding lack of healthy conjunctiva for AGV insertion sensitivity to betamethasone eye drop

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified block randomization was performed. We divided eyes into 2 subgroups as follow: group 1: patients undergone previous failed antiglaucoma surgery, group 2: patients without previous antiglaucoma surgery. In each subgroup, eyes are randomly assigned to the study arms using random blocks: totally 108 patients were enrolled dividing into 2 groups of conventional Ahmed Glaucoma Valve (AGV) implantation (group A, 54 eyes), Ahmed Glaucoma Valve (AGV) with pre-operative dropped betamethasone (group B, 54 eyes).

Blinding (investigator's opinion)

Double blinded

Blinding description

participants and data analyser were blinded in this study

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

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Shahid Hemmat Highway

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Tehran

Province

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Postal code

1449614535

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.413

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

first day, first week, month 1, 3, 6, 9 and 12 after the surgery

Method of measurement

Goldman applanation tonometry

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

number of eyes requiring medications

Timepoint

first day, first week, month 1, 3, 6, 9 and 12 after the surgery

Method of measurement

Quantitative

2**Description**

number of medications

Timepoint

first day, first week, month 1, 3, 6, 9 and 12 after the surgery

Method of measurement

Quantitative

3**Description**

Best corrected visual acuity (BCVA)

Timepoint

first day, first week, month 1, 3, 6, 9 and 12 after the surgery

Method of measurement

tumbling E-chart

4

Description

Complications

Timepoint

first day, first week, month 1, 3, 6, 9 and 12 after the surgery

Method of measurement

qualitative

Intervention groups

1

Description

Intervention group: pre-treatment with betamethasone eye drop 1% from 3 days before surgery until the time of surgery, 6 times a day in patients candidate for insertion of Ahmed valve in supra temporal area of eye

Category

Treatment - Drugs

2

Description

Control group: conventional insertion of Ahmed valve in supra temporal area of eye without pre-treatment betamethasone prescription

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Basir clinic

Full name of responsible person

Maryam Yadegari

Street address

4th floor, No 3, Shahid Sheibani Alley, after Keshavarz Blvd, Jamalzadeh Shomali St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Basir eye health research center

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

No funding source is applicable

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Basir eye health research center

Full name of responsible person

Maryam Yadegari

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Results will be shown in terms of published articles

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable