Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

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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Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Basir eye health research center
Full name of responsible person
Maryam Yadegari
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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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Person responsible for updating data

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Postal code
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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