

# 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

**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

###### **City**

Tehran

###### **Province**

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###### **Postal code**

1418643113

###### **Phone**

+98 21 4424 3894

###### **Email**

info@basirclinic.ir

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Basir eye health research center

###### **Full name of responsible person**

Maryam Yadegari

###### **Street address**

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###### **Province**

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###### **Phone**

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###### **Email**

info@behrc.ir

##### **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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sobhanisoheila@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Basir eye health research center

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Maryam Yadegari

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Professor

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## Person responsible for updating data

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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