

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of trabeculectomy with absorbable scleral flap sutures with trabeculectomy with releasable sutures in glaucoma patients

#### Protocol summary

##### Study aim

Comparison of trabeculectomy with absorbable scleral flap sutures with releasable sutures in glaucoma patients

##### Design

Study is a clinical trial with control group , parallel groups 20 patient without blinding, randomization based on the 4-way random permutations method.

##### Settings and conduct

In Imam Khomeini Hospital of Ahvaz, trabeculectomy is performed in 40 patients in two groups without blinding.

In the control group nylon releasable sutures and in the case group two absorbable sutures for scleral flap are used. The results and complications of surgery are compared in postoperative examination.

##### Participants/Inclusion and exclusion criteria

Inclusion criteriae: glaucoma patients referred to the ophthalmology center of Imam Khomeini Hospital in Ahvaz with indication of trabeculectomy for intraocular pressure control In these patients, intraocular pressure does not reach the target level with medication Exclusion crateriae: history of any intraocular surgery except cataract surgery history of extensive conjunctival injury use of antimetabolite or corticosteroid drugs History of collagenvascular disease History of uveitis, endophthalmitis or any ocular inflammation History of secondary glaucoma, congenital or neovascular glaucoma Black patients Patients with thin sclera

##### Intervention groups

In the case of trabeculectomy, the case group uses two polyglactin (Vicryl) 10.0 absorbable yarn sutures instead of non-absorbable sutures that will be completely covered with tenons and then conjunctiva. In the control group, trabeculectomy is performed with two releasable and nonabsorbable sutures.

##### Main outcome variables

post operative intraocular pressure, Visual Acuity, Ocular ant chamber depth, Other complications of trabeculectomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190909044735N1**

Registration date: **2020-09-20, 1399/06/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-20, 1399/06/30**

Update count: **0**

##### Registration date

2020-09-20, 1399/06/30

##### Registrant information

##### Name

Maliheh Darvishi Dastgerdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3223 2899

##### Email address

maliheh.darvishi.md@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of trabeculectomy with absorbable scleral flap sutures with trabeculectomy with releasable sutures in glaucoma patients

**Public title**

Trabeculectomy surgery study with Vicryl scleral flap sutures

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

glaucoma patients referred to the ophthalmology center of Imam Khomeini Hospital in Ahwaz with indication of trabeculectomy for intraocular pressure control In these patients, intraocular pressure does not reach the target level with medication

**Exclusion criteria:**

history of any intraocular surgery except cataract surgery history of extensive conjunctival injury use of antimetabolite or corticosteroid drugs History of collagenvascular disease History of uveitis, endophthalmitis or any ocular inflammation History of secondary glaucoma, congenital or neovascular glaucoma Black patients Patients with thin sclera

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Possibility of two-eye surgery from one person

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Subjects were randomly divided into two groups according to the four-way random permutations method. For example, if our blocks are 4, we have 6 blocks of AABB, ABAB, ABBA, BAAB, BAAB, BBAA, where we have to select n by dividing the 4 th sample by placement and thus obtain a randomization sequence. Randomization was achieved using WWW.sealedenvelope.com.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences Research

**Street address**

No.4, Ground Floor, Vice Chancellor for Research and Technology Development, Ahwaz Jundishapur University of Medical Sciences

**City**

Ahwaz

**Province**

Khuzestan

**Postal code**

6135715794

**Approval date**

2019-08-19, 1398/05/28

**Ethics committee reference number**

IR.AJUMS.REC.1398.413

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

Glaucoma

**ICD-10 code**

H40

**ICD-10 code description**

Glaucoma

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

post operative intraocular pressure

**Timepoint**

Intraocular pressure levels before surgery, morning after surgery, 3 days, one week, 2 weeks, 6 weeks and 3 months after surgery,

**Method of measurement**

The intraocular pressure will be measured by Goldman applan tonometer

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

Visual Acuity

**Timepoint**

postop day 7, 14 and 21

**Method of measurement**

Snellen

## 2

### Description

Ocular ant chamber depth

### Timepoint

postop day 1

### Method of measurement

with slit lamp examination

## 3

### Description

Other possible complications of trabeculectomy

### Timepoint

Morning after surgery, 3 days, one week, 2 , 6 weeks and 3 months after surgery.

### Method of measurement

in postop examination with slitlamp

## Intervention groups

### 1

#### Description

Intervention group: In trabeculectomy surgery scleral flap should be fixed with two sutures. In this group we use absorbable sutures from Vicryl that does not require postoperative suture removal.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Scleral flap sutures are as usual made from nylon, this sutures are releasable and should be removed in postoperative examinations.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital of Ahwaz

##### Full name of responsible person

Fereydoon Farhi

##### Street address

Ophthalmology Department, Imam Khomeini Hospital, 24 meter street.

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Ahwaz

##### Province

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##### Postal code

6193743954

##### Phone

+98 61 3223 2899

##### Email

maliheh.darvishi.md@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahwaz University of Medical Sciences

##### Full name of responsible person

Dr mohammad badavi

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Imam Khomeini Hospital, 24 meter street

##### City

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##### Province

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahwaz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Ahwaz University of Medical Sciences

##### Full name of responsible person

Fereidoon Farahi

##### Position

Associate Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Ophthalmology

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Ophthalmology Department, Imam Khomeini hospital, 24 meter street,

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##### Province

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Name of organization / entity**  
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farahi-f@ajums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Results of clinical examination after trabeculectomy in both case and control groups included intraocular pressure, visual acuity, anterior chamber depth changes, and any benefits or complications of trabeculectomy.

### When the data will become available and for how long

After the publication of the paper resulting from this research

### To whom data/document is available

Scholars who have access to the published article

### Under which criteria data/document could be used

Copyright

### From where data/document is obtainable

To the database of the journal in which the article is published

### What processes are involved for a request to access data/document

Refer to the journal's website and access the article according to the journal's terms

### Comments