

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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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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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

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Person responsible for updating data

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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