

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of results and complications of Phacoviscocanalostomy surgery with and without implants in patients with open angle glaucoma

Protocol summary

Study aim

Evaluation of the results and complications of 6-month Phacoviscocanalostomy with and without implants in patients with glaucoma

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, without instance of the trial phase on 60 patients. By simple randomization method, the subjects are divided into two groups of 30 intervention and control.

Settings and conduct

In this study, which is performed by clinical trial method, 60 patients with open-angle glaucoma referred to the ophthalmology clinic of Khatam-al-Anbia Hospital and with admission criteria by simple randomization method are divided into two groups that one group In addition to Viscocanalostomy,also subjected to intrascleral implantation using the remnants of Ahmed valve's tube.In the first three follow-ups, intraocular pressure(IOP), best corrected visual aquity(BCVA)and the number of drugs and in the sixth month follow-up, in addition to these cases, anterior segment optimal coherence tomography(AS OCT)is performed to check the area of the bleb.In this study, the subjects will not be aware of the use or non-use of implants and analysts will not be aware of patients' exposure or control. After collecting the data, we enter them into SPSS version 24 software and analyze them according to the objectives

Participants/Inclusion and exclusion criteria

Patient Satisfaction - Open Angle Glaucoma - Indication of Glaucoma Surgery - No Previous Surgery

Intervention groups

In this study, in the control group, only Viscocanalostomy was performed and in the intervention group, in addition to Viscocanalostomy, they underwent intrascleral implantation using the remnants of Ahmed valve's tube.

Main outcome variables

Preservation of intrascleral bleb; Improved fluid flow to suprachroidal flow; Implant availability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200704047997N1**

Registration date: **2020-11-08, 1399/08/18**

Registration timing: **retrospective**

Last update: **2020-11-08, 1399/08/18**

Update count: **0**

Registration date

2020-11-08, 1399/08/18

Registrant information

Name

Ali Bagheri Asl

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3728 9911

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of results and complications of Phacoviscocanalostomy surgery with and without implants in patients with open angle glaucoma

Public title

Comparison of results and complications of Phacoviscocanalostomy surgery with and without implants in patients with open angle glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient satisfaction Open angle glaucoma Indication of glaucoma surgery No previous surgery (glaucoma surgeries)

Exclusion criteria:

Complications during surgery Impossibility to follow up Lack of patient cooperation during follow-up

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method The envelope method will be used for random assignment of patients in study groups. In this way, random numbers will be prepared with the help of randomize.com and will be placed in sealed envelopes. The lid of the envelope is closed and the contents of the envelope will not be visible from the outside. The secretary of the clinic will deliver one of the envelopes to the patient and the surgeon will study the patient in one of the two groups based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Analysts will not know if patients are exposed or controlled. Subjects will not be aware of their exposure or control.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Aboutaleb Crossroads, Khatam Al-Anbia Ophthalmology Hospital

City

mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2019-12-18, 1398/09/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.672

Health conditions studied

1

Description of health condition studied

Open angle glaucoma

ICD-10 code

H40.1

ICD-10 code description

Open-angle glaucoma

Primary outcomes

1

Description

Bleb area measurement

Timepoint

Six months after surgery

Method of measurement

By anterior segment OCT

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, in addition to Phacoviscocanalostomy, they undergo intrascleral implants. In this intervention, a part of the Ahmed valve tube, which remains from the previous AGV operation and is practically useless, is sterilized and divided into two parts and the end 4 mm is cut. This tube is placed in the suprachroidal space.

Category

Treatment - Devices

2

Description

Control group: In this group, only Phacoviscocanalostomy is performed and no implant is used.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Ophthalmology Hospital

Full name of responsible person

Ali Bagheri Asl

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Bagheri Asl

Position

Resident of ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Person responsible for updating data

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Latest degree

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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

Not applicable

Title and more details about the data/document

All data can be shared

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

-

From where data/document is obtainable

Ali Bagheri Asl ali.bagheri7181@gmail.com

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

Send the request via email and state the reason for the request

Comments