Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)

Phone

+98 51 3728 9911

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ali.bagheri7181@gmail.com

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 glaoucoma 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 glaoucoma
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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Aboutaleb Crossroads, Khatam Al-Anbia Ophthalmology Hospital
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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
Street address
next to Hoa,veyzeh Cinem Ghorashi Building, Deputy of Research and Technology
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Tafaghodim@mums.ac.ir
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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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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