

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the surgical outcome of primary phaco-shunt versus primary phacotrabeculectomy in patients with concomitant cataract and glaucoma: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of success rate of primary phaco-shunt versus primary phacotrabeculectomy in patients with concomitant cataract and glaucoma

Design

A clinical trial study with two parallel groups, Randomized using computer permuted block randomization, There are 40 patients in each group and they are followed up for at least 6 months.

Settings and conduct

This study is performed on patients referred to the glaucoma clinic of Rasoul Akram Hospital in Tehran. Eligible patients are included in the study. First, the background information is recorded and thoroughly examined. Then they are randomly divided into two groups. Combined phacotrabeculectomy and phaco-shunt surgery are performed. In phaco-trab surgery, first cataract surgery is performed and then trabeculectomy is performed in the superior part. In phaco-shunt group, first shunt fixation and then cataract surgery are performed and then shunt tube is inserted into the eye. Then undergo regular examinations and two methods are compared in terms of success rate and possible complication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with concomitant glaucoma and cataract that need combined surgery, type of glaucoma is open angle glaucoma Exclusion criteria: Patients have more than 18 years old, type of glaucoma is other than open angle glaucoma, No history of glaucoma surgery

Intervention groups

In primary phaco-trab group, patients undergo combined phacoemulsification with trabeculectomy. In phaco-shunt group, patients undergo combined phacoemulsification with Ahmed Glaucoma Valve implantation.

Main outcome variables

Success rate; complication rate; Intra Ocular Pressure (IOP) before and after surgery; number of medication before and after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052357N1**

Registration date: **2022-01-04, 1400/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-04, 1400/10/14**

Update count: **0**

Registration date

2022-01-04, 1400/10/14

Registrant information

Name

Farhad Najafzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the surgical outcome of primary phaco-shunt versus primary phacotrabeculectomy in patients with concomitant cataract and glaucoma: A Randomized Clinical Trial

Public title

Comparison surgical outcome of primary phaco-shunt versus primary phacotrabeculectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with concomitant cataract and glaucoma that need combined surgery Type of glaucoma is open angle glaucoma

Exclusion criteria:

Patients have more than 18 years old Neovascular glaucoma Patients with No Light Perception (NLP) Diabetic patients with proliferative retinopathy or need frequent injection of IVB History of previous surgery: glaucoma surgery, retina surgery and scleral buckling History of cyclodestructive procedure Patients have scare of conjunctiva

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, we will use the random block method so that the number of samples in the two groups is the same. The blocks are considered as 4, with a and b representing the two study groups. All possible permutations for a block of 4 are as follows: aabb, abba, abab, bbaa, baab, baba. From these 6 permutations, one block will be selected at a simple random time. The reason for this is to reduce the likelihood that final allocations will be predictable. After selecting the block, the person will be assigned to group a or b in the same way.

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 Iran University of Medical Sciences

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No 18, Karimi Alley , Patris St, Sattarkhan St.

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Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.IUMS.REC.1400.433

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

Glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

2**Description of health condition studied**

Cataract

ICD-10 code

H25

ICD-10 code description

Age-related cataract

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

The primary outcome variable of this study is intraocular pressure, which is measured with a Goldmann Applanation Tonometer.

Timepoint

Preoperative intraocular pressure measurement and postoperative intraocular pressure measurements include: first day, first week, first month, third month, sixth month

Method of measurement

Intraocular pressure is measured using a Goldmann tonometer.

2

Description

Complications of combined surgery based on the type of surgical procedure.

Timepoint

Regular examinations after surgery include: first day, first week, first month and third month

Method of measurement

Through a thorough postoperative clinical examination.

Secondary outcomes

1

Description

Number of antiglaucoma drugs used before and after combination surgery.

Timepoint

Before surgery and 6 months after surgery

Method of measurement

By reviewing patient records

Intervention groups

1

Description

Intervention group: The group undergoing combined phaco-shunt surgery. In this method, Ahmad shunt valve model FP7 (New World Medical, LA) will be used, which is one of the most common shunts used in the world. First, the shunt is fixed and then cataract surgery is performed by phaco method. Finally, the shunt tube enters the eye and fixed with naylor 10.0 suture and then the conjunctiva close with 8-0 vicryl sutures . Postoperative patients undergo regular examinations according to a specific protocol to evaluate the effectiveness as well as possible complications.

Category

Treatment - Surgery

2

Description

Intervention group: The group undergoing combined phacotrabeculectomy surgery. In this method, patients are first subjected to cataract surgery by phaco method. Then trabeculectomy in the superior region begins with conjunctival peritomy. Then MMC material with a dose of 0.04% for 2 minutes is used to reduce postoperative fibrosis. Finally, a sclera flap is created and a keratectomy and an iridectomy are performed, and all incisions are closed with nylon 10.0 sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

glaucoma clinic of Rasoul Akram Hospital in Tehran

Full name of responsible person

Farhad Najafzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motavallian

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Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Farhad Najafzadeh

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available