

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Outcomes and Complications of Phaco-Trabeculectomy (PT) With Phaco-Viscocanalostomy (PVC) in glaucoma patients: a single blind randomized controlled trial

Protocol summary

Study aim

Comparison of Outcomes And Complications of Phaco-Trabeculectomy (PT) With Phaco-Viscocanalostomy (PVC)

Design

A randomized, single-blind, clinical trial of 60 patients. Minim software was used for randomization.

Settings and conduct

60 people who referred to the ophthalmology clinic of Shafa Hospital in Kerman (30 participants in the PT group and 30 participants in the PVC group) will be selected based on the inclusion criteria. After obtaining informed consent, a complete eye examination including visual acuity, IOP assessment, and gonioscopy will be performed by a glaucoma specialist. After the surgery, the consequences and complications of the operation will be evaluated in the first, fourth and sixth weeks after the operation. This is a single blind study since the patient, eye surgeon and data collector should be aware of the type of surgery, but Information will be kept confidential from the statistician.

Participants/Inclusion and exclusion criteria

The study population: all glaucoma patients referred to the ophthalmology clinic that are candidates for phacoemulsification surgery (for the treatment of cataracts) + glaucoma surgery (Trabeculectomy or Viscocanalostomy).

Intervention groups

Phycoviscocanalostomy: applying two scleral flaps, exposure of the schlemm canal, injection of the hyaluronic acid gel for 5-6 times, suturing the flaps, no need for a conjunctival bleb. Phycotrabelectomy: Periotomy and separation of the conjunctiva and tenon from the sclera, removal of the scleral flap close to the limbus, placing mitomycin c under the conjunctiva and tendon for 1.5 minutes, and irrigation, removal of the scleral block by 1× 1 mm and Peripheral iridectomy, suturing the scleral flap, suturing the limbal conjunctiva

Main outcome variables

Comparison of IOP, Visual Acuity, early and late postoperative complications, and intraoperative complications in PT and PVC methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220116053736N1**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **prospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Mahdi Sharifzadeh Kermani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3211 5794

Email address

mehdisharifzade818@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Outcomes and Complications of Phaco-Trabeculectomy (PT) With Phaco-Viscocanalostomy (PVC) in glaucoma patients: a single blind randomized controlled trial

Public title
Comparison of Outcomes and Complications of Phaco-Trabeculectomy (PT) With Phaco-Viscocanalostomy (PVC) in glaucoma patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Glaucoma of Primary Open-Angle Glaucoma (POAG), Pseudoexfoliative Glaucoma (PXG), Chronic Angle Closure Glaucoma (CACG) uncontrolled with at least 2 topical medications (0.5% thymolol drops, 2 times a day) and dorzolamide 3 times daily (IOP > 21 mm Hg). Glaucoma of Primary Open-Angle Glaucoma (POAG), Pseudoexfoliative Glaucoma (PXG), Chronic Angle Closure Glaucoma (CACG) Despite using several anti-glaucoma drugs. Significant cataract (BCVA ≤20 / 60) justified by lens opacity.
Exclusion criteria:
 History of intraocular surgery such as vitreous and retinal surgery Phacomorphic glaucoma Significant corneal opacity Secondary glaucoma (Uveitis Glaucoma, neovascular glaucoma, pigmentary glaucoma) Diabetic retinopathy History of eye trauma Posterior chamber eye diseases History of phacoemulsification (PE) and glaucoma surgeries Incomplete participants' information (> 10%) Signing the written informed consent

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
To randomize the participants, minimization method was used (randomization unit: individual). The random sequence was built with Minim software. In this study the allocation concealment was carried out too.

Blinding (investigator's opinion)
Single blinded

Blinding description
The blinding method in this study will be single blind because the patient, eye surgeon (glaucoma specialist)

and data collector (clinical assistant of eye diseases) must be aware of the type of surgery. But the information from the statistician will be kept secret. In this regard, the data gatherer will randomly name the intervention and control group A or B by and send the patients data to the statistician.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Haft Bagh Alavi Blvd, campus of University of Medical Sciences

City

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Postal code

7616913555

Approval date

2021-12-28, 1400/10/07

Ethics committee reference number

IR.KMU.AH.REC.1400.232

Health conditions studied

1

Description of health condition studied

Glaucoma is a group of disorders that differ in their pathophysiology, risk factors, manifestations, treatments, and prognoses. Their common feature is progressive degeneration of the optic nerve, with loss of retinal ganglion cells, thinning of the retinal nerve fiber layer, and progressive excavation of the optic disc.

ICD-10 code

H44.51

ICD-10 code description

Absolute glaucoma

2

Description of health condition studied

A cataract is a cloudy area in the lens of the eye that leads to a decrease in vision. It often develop slowly and can affect one or both eyes.

ICD-10 code

H26.9

ICD-10 code description

Unspecified cataract

Primary outcomes

1

Description

Intraocular pressure (IOP)

Timepoint

At the beginning of the study (before the intervention), in the first and fourth weeks, and sixth months after surgery

Method of measurement

Goldmann tonometry

2

Description

Number of drops used to reduce IOP

Timepoint

Before intervention, 1 and 4 weeks and 6 months after intervention

Method of measurement

The designed checklist

3

Description

Intraoperative complications

Timepoint

From the beginning to the end of the surgery

Method of measurement

Examination by a glaucoma subspecialist

4

Description

Postoperative early complications

Timepoint

In 1 and 4 weeks following surgery

Method of measurement

Examination by a glaucoma subspecialist

5

Description

Postoperative late complications

Timepoint

Six months after surgery

Method of measurement

Examination by a glaucoma subspecialist

6

Description

Visual Acuity

Timepoint

Before intervention, 1 and 4 weeks and 6 months after surgery

Method of measurement

Snellen chart

Secondary outcomes

1

Description

Need to use antiglaucoma drugs after surgery

Timepoint

In the first and fourth weeks and the sixth month after surgery

Method of measurement

Examination by a glaucoma subspecialist

Intervention groups

1

Description

Intervention group: First group: The first group underwent phaco-trabeculectomy (PT) surgery, in which after phycoemulsification (PE), a limbus block measuring 1×1 mm will be removed from the scleral flap. After removal of the viscoelastic material, acetylcholine chloride 1% will be injected to create pupillary stenosis and peripheral iridectomy will be performed. Two sutures with 10-0 nylon threads on both sides tightens the scleral flap. The conjunctiva will then will be sutured to the limbus with 10-0 nylon thread.

Category

Treatment - Surgery

2

Description

Intervention group: Second group: The second group will undergo Visco canalostomy (PVC) surgery. After phycoemulsification (PE), dissection of a 4× 4-mm triangular scleral flap underneath a 5× 5 mm superficial flap will derroof Schlemm's canal. The inner scleral flap will be pulled upward, and the floor of the canal and Descemet's membrane will be depressed with the tip of a cellulose sponge. The membrane was then cleaved from the cornea for a distance of about 1 mm. Afterwards, the inner scleral flap will be excised. After cannulation and assurance from correct positioning, the proximal ends of the Schlemm's canal, as well as the intrascleral space, will be filled with sodium hyaluronate according to Stegmann's technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Mahdi Sharifzadeh Kermani

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1

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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
Kerman 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
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Position
Assistant professor
Latest degree
Subspecialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available