

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of anterior segment morphological changes using anterior segment optical coherence tomography (ASOCT) in patients with coexisting primary angle closure glaucoma and cataract, undergoing phacoemulsification and phacotrabeculectomy.

Protocol summary

Study aim

Investigation of anterior segment morphological changes using anterior segment optical coherence tomography in patients with coexisting primary angle closure glaucoma and cataract, undergoing either phacoemulsification or phacotrabeculectomy.

Design

Two-arm, parallel groups randomized clinical trial. The observer was masked to the study group; however, the participants were not blinded. Randomization was done with random-digit table.

Settings and conduct

Consecutive, eligible patients, consented to participate in the study in Glaucoma Clinic, Khatam Eye Hospital, Mashhad University of Medical Sciences, enters the study and randomly allocate to the study groups. Outcome measures are evaluated at postoperative 1 week, 1 month and 6 months intervals.

Participants/Inclusion and exclusion criteria

Patients with coexisting primary angle closure glaucoma and cataract, requiring surgical intervention, and without a history of previous intraocular surgery or other ocular diseases.

Intervention groups

Group A, Phacoemulsification. In this group, patient undergo standard phacoemulsification cataract surgery with foldable intraocular lens implantation. Group B, Phacotrabeculectomy. In this group, patients undergo phacoemulsification cataract surgery and foldable intraocular lens implantation with concurrent fornix based trabeculectomy with releasable sutures and intraoperative mitomycin-C application.

Main outcome variables

1. Intraocular pressure 2. Angel opening distance 3. Trabecular iris surface area 4. Trabecular iris angle

General information

Reason for update

There are typos in entering the trial recruitment's start and end dates. Recruitment was started after approval by the Ethical Committee.

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001154N2**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **retrospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **1**

Registration date

2020-10-07, 1399/07/16

Registrant information

Name

Ramin Danehvar

Name of organization / entity

Eye Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-06-20, 1394/03/30

Expected recruitment end date

2016-12-19, 1395/09/29

Actual recruitment start date

2015-08-21, 1394/05/30

Actual recruitment end date

2017-02-01, 1395/11/13

Trial completion date

2017-03-03, 1395/12/13

Scientific title

Comparison of anterior segment morphological changes using anterior segment optical coherence tomography (ASOCT) in patients with coexisting primary angle closure glaucoma and cataract, undergoing phacoemulsification and phacotrabeculectomy.

Public title

Anterior segment parameters following surgical management in angle closure glaucoma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary angle closure glaucoma Cataract

Exclusion criteria:

Any previous intraocular surgery (except laser iridotomy)
History of ocular trauma History of other ocular diseases (except cataract and glaucoma)

AgeFrom **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60**Actual sample size reached: **52****Randomization (investigator's opinion)**

Randomized

Randomization description

Envelops, containing random numbers were prepared and sealed. To pick the number, the first number was selected by a pen with closed eyes and then successive numbers were selected from the table (eg, if the first number was 7, we moved to the right and down of that digit and selected every 7th number to reach the required 60 envelopes with random numbers). For each participants, a new envelope was opened and those with odd number allocate to phacoemulsification group and those with even number allocated to the phacotrabeculectomy group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The main purpose of the study is to investigate the effect of either surgical method on the anterior chamber drainage angle.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

91375345

Approval date

2015-05-21, 1394/02/31

Ethics committee reference number

IR.MUMS.REC.1394.262

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**

Intraocular pressure (IOP)

Timepoint

Postoperative 1st week, 1st month, 6th and month

Method of measurement

IOP measurement with Goldmann applanation tonometer

2**Description**

Angle opening distance at 500 micron (AOD500)

Timepoint

Before surgery, 1 week, 1 month and 6 months after

surgery
Method of measurement
Measuring AOD using Casia AS-OCT device (Tomey)

3

Description
Trabecular iris angle at 500 micron (TIA500)
Timepoint
Before surgery; 1 week, 1 month and 6 months after surgery
Method of measurement
Measuring TIA using Casia ASOCT (Tomey)

4

Description
Trabecular-iris surface area (TISA)
Timepoint
Before surgery; 1 week, 1 month and 6 months after surgery
Method of measurement
Measuring TIA using Casia ASOCT (Tomey)

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, the patients undergo phacoemulsification cataract surgery with a temporal incision and posterior chamber intraocular lens (PCIOL) implantation in the capsular bag. At the conclusion of cataract surgery and in the same session, a superior fornix-based trabeculectomy with intraoperative mitomycin-c is done for the patients.
Category
Treatment - Surgery

2

Description
In the control group, the patients undergo temporal phacoemulsification and in the bag PCIOL implantation. No separate, additional glaucoma surgery is done in this group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Eye Hospital
Full name of responsible person
Ramin Daneshvar, MD, MSc
Street address

Gharani Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
<https://v-research.mums.ac.ir/>
Grant name
Grant code / Reference number
930126
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

Ramin Daneshvar, MD, MSc

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Ramin Daneshvar, MD, MSc

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

Deidentified, anonymous participants data are available in a MS Excel file.

When the data will become available and for how long

One year after publication of the article.

To whom data/document is available

Other researcher, upon written request

Under which criteria data/document could be used

Accreditation and meta-analysis

From where data/document is obtainable

Written request, directed to corresponding person or PI

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

Upon approval of the request by Vice chancellor of Research at MUMS and the legal authorities, the information would be sent to the requester.

Comments