Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A clinical trial comparing the effectiveness of simultaneous pterygium excision and phacoemulsification with separate procedures on visual outcomes in patients with concurrent pterygium and cataract

Protocol summary

Study aim

To compare the effectiveness of simultaneous pterygium excision and phacoemulsification with separate procedures on visual outcomes in patients with concurrent pterygium and cataract

Design

This randomized and single-blind clinical trial with parallel and two intervention groups will be conducted on 30 patients who will be randomly selected using the blocks.

Settings and conduct

Patients will be recruited from Shahid Beheshti Ophthalmology Clinic in Karaj and Karaj Social Security Hospitals. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group 1 will undergo simultaneous pterygium excision and phacoemulsification, while intervention group 2 will receive the two procedures sequentially, with a one-month interval between surgeries. The person responsible for data collection is blind to group allocation and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 50 years; patients diagnosed with cataracts and pterygium; having full consent to participate in the study. Exclusion criteria: Having severe pterygium; having corrected distance visual acuity (CDVA) exceeding 0.15 logMAR; having unreliable refractive measurements; history of ocular surgery or traumatic eye injury, or coexisting ocular pathologies other than pterygium and cataract.

Intervention groups

The intervention group 1, Participants will undergo pterygium excision and phacoemulsification in a single operative session. The intervention group 2, Participants will first undergo pterygium excision, followed by phacoemulsification surgery after a one-month interval.

Main outcome variables

Evaluation and comparison of best corrected visual acuity, astigmatism, and keratometry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161106030746N2**
Registration date: **2025-11-02, 1404/08/11**
Registration timing: **prospective**

Last update: **2025-11-02, 1404/08/11**
Update count: **0**

Registration date

2025-11-02, 1404/08/11

Registrant information

Name
Nima Rastgar Rad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6692 0178
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rrnima88@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effectiveness of simultaneous pterygium excision and phacoemulsification with separate procedures on visual outcomes in patients with concurrent pterygium and cataract

Public title

The effectiveness of simultaneous pterygium excision and phacoemulsification on visual outcomes in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 50 years Patients diagnosed with cataracts and pterygium Having full consent to participate in the study

Exclusion criteria:

Having severe pterygium Having corrected distance visual acuity (CDVA) exceeding 0.15 logMAR Having unreliable refractive measurements History of ocular surgery or traumatic eye injury, or coexisting ocular pathologies other than pterygium and cataract

Age

From **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be enrolled by one of the research colleagues. A person, blinded to group allocation will provide a random allocation sequence using computer software of SAS prior to the initiation of the study to be used to randomize participants with 1:1 allocation ratio. A block randomization design (block size of 4, 6) will be applied to ensure an equal number of participants in each group. Group allocation will be concealed in sequentially numbered, opaque, sealed envelopes, and corresponding envelopes will be opened after the enrolled participants are analyzed. In this study the instructor and participants will not be blinded to the group allocation but care provider and responsible for data collection will be blinded to the group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind in which both researchers and patients are unaware of the allocation. Upon completion of the study and collection of results, the corresponding codes for each patient will be provided to the specialized team. The single-blind nature of the study was maintained by ensuring that the clinical supervisor and the individual responsible for data collection were not privy to the patients' allocation. Consequently, the results will be presented anonymously and in a coded format.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Office of the Ethics Committee, Second Floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2025-07-15, 1404/04/24

Ethics committee reference number

IR.ABZUMS.REC.1404.172

Health conditions studied

1

Description of health condition studied

Pterygium

ICD-10 code

H11.0

ICD-10 code description

Pterygium of eye

2

Description of health condition studied

Cataract

ICD-10 code

H26.9

ICD-10 code description

Unspecified cataract

Primary outcomes

1

Description
Corrected visual acuity
Timepoint
Before, 1, 2, and 3 months after intervention
Method of measurement
Snellen chart

2

Description
Astigmatism
Timepoint
Before, 1, 2, and 3 months after intervention
Method of measurement
Refraction test

3

Description
keratometry
Timepoint
Before, 1, 2, and 3 months after intervention
Method of measurement
Keratometer device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group 1, Participants will undergo pterygium excision and phacoemulsification in a single operative session.
Category
Treatment - Surgery

2

Description
Intervention group: The intervention group 2, Participants will first undergo pterygium excision, followed by phacoemulsification surgery after a one-month interval.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Karaj Clinic
Full name of responsible person
Nima Rastgar Rad
Street address
Shahid Beheshti Clinic, before reaching Shohada Square, Shahid Beheshti Street
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3153848161
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2

Recruitment center
Name of recruitment center
Social Security Hospital
Full name of responsible person
Nima Rastgar Rad
Street address
Alborz Specialized Hospital, located at the West Garden, at the end of Parast Boulevard
City
Karaj
Province
Alborz
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5551897377
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Nori Sepehr
Street address
Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr
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3198764653
Phone
+98 26 3464 3705
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Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Nima Rastgar Rad
Position
Non-academic specialist
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
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Alborz University of Medical Sciences, Taleghani Boulevard, Taleghani square, Karaj, Iran
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The research data obtained from the main outcomes of the study can be shared freely as 'open data'.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Nima Rastgar Rad provides the data analysis to the applicants via email: rrnima88@gmail.com

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

Applicants can send emails to him and receive a response within a week.

Comments