Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

the effect of pilocarpine 1% eye drop on the relative improvement of presbyopia

Protocol summary

Study aim
Determining the efficacy of 1% pilocarpine eye drops in the relative improvement of symptoms in Patients with presbyopia.

Design
A community-based, practice-oriented, parallel-group, triple-blind, randomized controlled clinical trial

Settings and conduct
This study will be conducted on 60 patients referred to Shahid Sadoughi Hospital in Yazd diagnosed with presbyopia. The uncorrected near visual acuity and uncorrected distance visual acuity of the patients is checked and recorded with the Snellen chart, then the patients are divided into two groups A and B using a random table of numbers from 1 to 60, and each number is randomly assigned to one group (A or B) . For each patient, the corresponding drop is prescribed. After starting the treatment, his visual acuity will be re-measured based on the times mentioned in the goals. (In order for the study to be a three-blind study, pilocarpine 1% drops and Tearlose drops are prepared by the pharmacist of the Shahid Sadoughi Hospital pharmacy in the same package labeled A or B, and only the pharmacist knows the type of drops. (The researcher, the patient and the statistical consultant are not informed).

Participants/Inclusion and exclusion criteria
Patients 40-60 years old with presbyopia who consent to participate in the study. Exit criteria: Presence of other simultaneous eye diseases (Amblyopia - Corneal opacity - Cataract - Glaucoma - High myopia - Retinal disorders - Eye surgeries and eye trauma) Severe sensitivity and side effects to eye drops Taking drugs that interact with pilocarpine (including amitriptyline, nortriptyline, doxepin and other drugs that affect the brain and nervous system)

Intervention groups
1) The intervention group treated with 1% pilocarpine eye drops 2) control group treated with artificial tear eye drops (tearlose)

Main outcome variables
uncorrected visual acuity (near and distance)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240325061363N1**
Registration date: **2024-04-20, 1403/02/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-20, 1403/02/01**
Update count: **0**

Registration date
2024-04-20, 1403/02/01

Registrant information

Name
Mohammad hossein Abutorabi zarchi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-06, 1403/01/18

Expected recruitment end date
2024-12-20, 1403/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
the effect of pilocarpine 1% eye drop on the relative improvement of presbyopia

Public title
the effect of pilocarpine 1% eye drop on the relative improvement of presbyopia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 40-60 years Suffering from presbyopia Uncorrected near visual acuity: 20/40 to 20/100

Exclusion criteria:
Eye diseases (including glaucoma, cataracts, amblyopia, high myopia, eye trauma, congenital pupil abnormalities, corneal opacity, intraocular surgeries) Severe sensitivity and side effects to eye drops Taking drugs that interact with pilocarpine

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups A and B using a random table of numbers from 1 to 60 and each number will be randomly assigned to a group (A or B) and the corresponding drops will be prescribed for each group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order for the study to be three-way blind, pilocarpine 1% drops and Tearlose artificial tears drops are prepared by the pharmacist of Shahid Sadouqi Hospital pharmacy (Mr. Dr. Fallah) in the same packaging with A or B stickers, and only he knows The type of drops A and B (researcher, patient and statistical consultant are not informed) and after collecting and announcing the results, the type of drops will be determined (announced) and the general statistical results will be reported based on the type of drops used by the patients.

Placebo
Used

Assignment
Parallel

Other design features
After the patient consumes the drops, his uncorrected near visual acuity and uncorrected far visual acuity are measured again based on the times mentioned in the goals, and on the 30th day after examination with a slit lamp, the side effects of the drug are also measured.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of school of medicine-Shahid Sadoughi University of Medical Sciences

Street address
Vice President of Research and Technology of yazd Shahid Sadougi University of Medical Sciences, Imam Reza Research Educational Complex, Student Blvd., Imam Hossein Square, Yazd

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Approval date
2024-03-13, 1402/12/23

Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.405

Health conditions studied

1

Description of health condition studied
presbyopia

ICD-10 code
H52.4

ICD-10 code description
Presbyopia

Primary outcomes

1

Description
Uncorrected near visual acuity and uncorrected distance visual acuity

Timepoint
Before the intervention, 20 minutes later, one hour and six hours later, as well as on the 14th and 30th days

Method of measurement
Snellen chart

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: sterile eye drops Pilocarpine 1% (Sina darou company) every morning, one drop in each eye for one month
Category
Treatment - Drugs

2

Description
Control group: sterile eye drops Tearlose (Sina darou company) every morning, one drop in each eye for one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yard Shahid Sadoughi Hospital
Full name of responsible person
Mohammad hosein Abutorabi zarchi
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Shahid sadoughi Hospital, Ibn Sina Street, Shahid Ghandi Boulevard, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohammad hosein Abutorabi zarchi
Position
Resident
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

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

Title and more details about the data/document

Clinical study report

When the data will become available and for how long

After completing the study and printing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

As a review of texts in other articles

From where data/document is obtainable

responsible author

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

Follow up via email of the responsible author

Comments