Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Influence of Dry Eye Disease and Artificial Tear eye drop on the Biometry Repeatability and Accuracy in Patients with Cataract

Protocol summary

Study aim

Determining the Influence of Dry Eye Disease and Artificial Tear eye drop on the Biometry Repeatability and Accuracy in Patients with Cataract in the ophthalmology clinic of Farshchian (Sina) Hospital in 2024-2025

Design

Clinical trial in a group of 20 bilateral cataract surgery candidates (40 eyes) with dry eye disease referred to Hamedan Sina Hospital in 2024-25, with a control group, with parallel groups, not randomized and without blinding

Settings and conduct

In patients aged 50 to 70 years with bilateral cataracts, routine preoperative examinations will be performed. Schirmer test, TBUT test, and corneal staining will be used to determine the presence and severity of dry eye disease. Biometry will be performed twice using IOLMaster 500, 15 minutes apart, for one eye without artificial tears and ten minutes after applying artificial tear drop in the opposite eye, and this will be repeated. All patients will undergo Phaco cataract surgery under local anesthesia, and one month after surgery, patients' refraction will be measured and their spherical equivalent will be compared with the expected one.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Patients aged 50 to 70 years with bilateral cataracts and mild to moderate dry eye disease without any pathology affecting biometry or prior ocular surgery and with consent to participate in the study Exclusion criteria:Any complications during or after surgery or failure to attend follow-up visits

Intervention groups

Patients aged 50 to 70 years with bilateral cataracts and mild to moderate dry eye disease will be instilled with artificial tear drop in one eye before biometry, and the patient's refraction will be measured and the patients' SE will be compared with the expected SE in both eyes one month later.

Main outcome variables

Axial length;Anterior chamber depth;Corneal astigmatism;Mean keratometry; Spherical equivalent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250714066483N1**
Registration date: **2025-10-30, 1404/08/08**
Registration timing: **retrospective**

Last update: **2025-10-30, 1404/08/08**
Update count: **0**

Registration date

2025-10-30, 1404/08/08

Registrant information

Name
Elham Soltani
Name of organization / entity
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Iran (Islamic Republic of)
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e.soltani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-10-07, 1404/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Influence of Dry Eye Disease and Artificial Tear eye drop on the Biometry Repeatability and Accuracy in Patients with Cataract

Public title

Investigating the Influence of Dry Eye Disease and Artificial Tear eye drop on the Biometry Repeatability and Accuracy in Patients with Cataract

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 50 to 70 years with bilateral cataract and mild to moderate Dry eye disease Informed consent to participate in the study Absence of pathologies influencing biometry such as keratoconus, corneal scar, pathologic myopia, nanophthalmus, etc Absence of prior ocular surgical history

Exclusion criteria:

Any intra- or postoperative complication occurance Patient's failure to attend follow-up visit

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

both eyes in a patient with bilateral cataract and dry eye disease

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Hamedan university of medical sciences

Street address

Hamedan University of Medical Sciences, Shahid Fahmid Blvd., Pajouhesh Square

City

Hamedan

Province

Hamadan

Postal code

6517838736

Approval date

2025-02-16, 1403/11/28

Ethics committee reference number

IR.UMSHA.REC.1403.837

Health conditions studied

1

Description of health condition studied

cataract

ICD-10 code

H26

ICD-10 code description

Other cataract

2

Description of health condition studied

Dry eye disease

ICD-10 code

H04.12

ICD-10 code description

Dry eye syndrome

Primary outcomes

1

Description

spherical equivalent

Timepoint

At the beginning of the study and one month after surgery

Method of measurement

Topcon RM8000 autorefractometer

2

Description

Anterior chamber depth

Timepoint

At the beginning of the study and one month after surgery

Method of measurement

IOL Master 500

3

Description

Axial length

Timepoint
At the beginning of the study and one month after surgery
Method of measurement
IOL Master 500

4

Description
mean keratometry
Timepoint
At the beginning of the study and one month after surgery
Method of measurement
Topcon RM8000 autorefractometer

5

Description
corneal astigmatism
Timepoint
At the beginning of the study and one month after surgery
Method of measurement
Topcon RM8000 autorefractometer

6

Description
Dry eye disease severity
Timepoint
before intervention
Method of measurement
Schirmer test, TBUT test, and corneal staining

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: primary biometry using IOLMaster-500 and then Instilling tearlose (Sinadaro) artificial tear drop 10 minutes before second biometry in one of a patient's eyes and one month after cataract surgery, measuring refraction and SE using auto refractometer
Category
Prevention

2

Description
Control group: primary biometry using IOLMaster-500 and then not instilling Tearlose (Sinadaro) artificial tear drop 10 minutes before second biometry in one of a patient's eyes and one month after cataract surgery, measuring refraction and SE using auto refractometer
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina (Farshchian) hospital
Full name of responsible person
Elham Soltani
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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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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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Position
Associate
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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