

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 81 3826 5706

Email address

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 occurrence 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

Street address

Pastor Crossroads

City

Hamedan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3825 4083

Fax

+98 81 3825 4083

Email

e.soltani@umsha.ac.ir

Web page address

<https://fsh.umsha.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Alireza Soltanian

Street address

Vice President of Research and Technology office, university headquarters 4th floor, Shahid Fahmideh Blvd.

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۶۸۳۸۷۴

Phone

+98 81 3131 4058

Fax

+98 81 3131 4058

Email

Fanavari@umsha.ac.ir

Web page address

<https://research.umsha.ac.ir/>

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

Postal code

6516848741

Phone

+98 81 3826 5706

Fax**Email**

e.soltani@umsha.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Elham Soltani

Position

Associate

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Mirzadeh Eshghi street , Farshchian (Sina) Hospital

City

Hamadan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3826 5706

Fax**Email**

e.soltani@umsha.ac.ir

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

Hamedan University of Medical Sciences

Full name of responsible person

Elham Soltani

Position

Associate

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Mirzadeh Eshghi street , Farshchian (Sina) Hospital

City

Hamadan

Province

Hamadan

Postal code

6516848741

Phone

+98 81 3826 5706

Fax**Email**

e.soltani@umsha.ac.ir

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

Hamedan University of Medical Sciences

Full name of responsible person

Elham Soltani

Position

Associate

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Mirzadeh Eshghi street , Farshchian (Sina) Hospital

City

Hamadan

Province

Hamadan

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