Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy and safety of topical statin eye drop compared to placebo in the management of dry eye associated with meibomian gland dysfunction

Protocol summary

Study aim

Efficacy and Safety of Topical Statin Eye Drop in the Management of Dry Eye Associated with Meibomian Gland Dysfunction (MGD)

Design

This double-blind, randomized clinical trial will include patients aged 40–65 with dry eye symptoms and TBUT < 10 seconds. After an initial safety phase on 10 volunteers, eligible patients will be consecutively enrolled and randomly assigned to receive either topical atorvastatin or placebo drops in one eye. Both groups will also undergo standard treatment with eyelid hygiene and warm compresses for 12 weeks. Outcomes including TBUT, Schirmer test, fluorescein staining, OSDI, DEQ5 scores, and meibomian gland expressibility will be evaluated at baseline and weeks 4, 8, and 12.

Settings and conduct

This randomized, double-blind clinical trial will be conducted at Shahid Labafi Nejad Hospital. A blinded ophthalmologist will perform all evaluations, and treatment codes will remain sealed until after the final data analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 40–65 years who exhibit dry-eye symptoms and have a TBUT of < 10 seconds attributable exclusively to MGD. Exclusion criteria: Patients whose symptoms are caused by or occur alongside any other ocular disease

Intervention groups

Intervention group: Standard MGD treatment (eyelid hygiene) plus topical atorvastatin (50 µM), administered as one drop four times daily in one eye. Control group: Standard MGD treatment (eyelid hygiene) plus placebo eye drops, administered as one drop four times daily in one eye.

Main outcome variables

OSDI Questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250513065716N1**
Registration date: **2025-09-11, 1404/06/20**
Registration timing: **prospective**

Last update: **2025-09-11, 1404/06/20**
Update count: **0**

Registration date

2025-09-11, 1404/06/20

Registrant information

Name

Salar Bahrami

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of topical statin eye drop compared to placebo in the management of dry eye associated with meibomian gland dysfunction

Public title
Effect of Atorvastatin in treatment of MGD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 40–65 years Individuals exhibiting symptoms of dry eye and a tear break-up time (TBUT) of less than 10 seconds, attributable exclusively to Meibomian gland dysfunction
Exclusion criteria:
Oral statin administration Use of doxycycline or other medications affecting MGD, such as azithromycin Unwillingness to participate in the study Hematologic or coagulation disorders; use of anticoagulant medications such as warfarin or Coumadin History of peptic ulcer disease Presence of concurrent ocular malignancies History of ocular surgery within the past three months History of ocular trauma
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Type of Randomization: We used simple randomization with an individual unit of allocation. Randomization Sequence Generation: The random allocation sequence was generated using a computer-generated random number table. Allocation Concealment: Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE), which were prepared by an independent assistant not involved in the study. Stratification: No stratified or block randomization was used in this study. The randomization procedure was designed in consultation with an epidemiologist to ensure methodological rigor.
Blinding (investigator's opinion)
Double blinded
Blinding description
Neither participants nor the clinical evaluator will know whether the administered eye drop contains topical statin or placebo. both formulations have identical appearance, color, odor, viscosity, and packaging, and will be labeled with random allocation codes generated by a statistician who is otherwise uninvolved in the study. Assignment of each bottle to individual subjects will follow the permuted-block randomization list; only the pharmacist responsible for labeling and an independent data-safety officer will have access to the code key. All ocular examinations and outcome assessments will be performed by a single cornea specialist masked to group allocation. The randomization code will remain sealed until after completion of data collection and primary statistical analysis, except in the event of a serious adverse event that requires unblinding for patient safety.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
6th Floor, University Headquarters Building No. 2, Shahid Beheshti University of Medical Sciences and Health Services, E'arabi Street, Yemen Street, Shahid Chamran Expressway
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Approval date
2023-10-08, 1402/07/16
Ethics committee reference number
IR.SBMU.ORC.REC.1402.018

Health conditions studied

1

Description of health condition studied
Meibomian Gland Dysfunction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Ocular surface disease index (OSDI) score
Timepoint
Measurement of the OSDI questionnaire score at baseline (prior to the intervention) and at weeks 4, 8,

and 12 after initiation of the drug or placebo

Method of measurement

Ocular surface disease index is a questionnaire that assesses ocular symptoms, visual function, and environmental aggravating factors related to dry eye disease.

Secondary outcomes

1

Description

Tear break up time (TBUT)

Timepoint

Measurement of TBUT at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

The time interval between fluorescein staining of the conjunctival cul-de-sac and the appearance of the first dry spot on the corneal surface.

2

Description

The number of stained spots on the cornea and conjunctiva observed during fluorescein staining.

Timepoint

Measurement of Fluorescein staining at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

The number of stained spots on the cornea and conjunctiva, evaluated according to the Oxford grading scale.

3

Description

The length in millimeters of a standard filter paper strip wetted by the patient’s tears after 5 minutes (Schirmer test)

Timepoint

Measurement of Schirmer test at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

Schirmer test: The length, in millimeters, of a standard Schirmer strip wetted by the patient's tear fluid after 5 minutes

4

Description

Dry eye questionnaire (DEQ5) score

Timepoint

Measurement of DEQ5 score at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

A self-administered questionnaire used to assess the presence and severity of dry eye symptoms.

5

Description

Meibomian gland expressibility

Timepoint

Measurement of Meibomian gland expressibility at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

Evaluation of the meibomian glands in the lower eyelid is performed by applying approximately 1.20 grams per square millimeter of pressure to the nasal, central, and temporal regions. Lipid secretion from the gland orifices is assessed and graded on a scale from 0 to 4:Grade 0: secretion from more than 75% of the glands; Grade 1: secretion from 50–75% of glands; Grade 2: secretion from 25–50% of glands; Grade 3: secretion from less than 25% of glands; Grade 4: no secretion from any gland. In addition, the quality of the expressed meibum is graded as follows: Grade 0: clear; Grade 1: cloudy; Grade 2: cloudy with debris or granular texture;G rade 3: thick and toothpaste-like; Grade 4: waxy

6

Description

Tear meniscus height

Timepoint

Measurement of Tear meniscus height at baseline (prior to the intervention) and at weeks 4, 8, and 12 after initiation of the drug or placebo.

Method of measurement

Measurement of tear film height using the slit-lamp biomicroscope.

Intervention groups

1

Description

Intervention group: one affected eye of each patient will be enrolled in the study as the treatment eye. In addition to standard care, including eyelid hygiene and warm compresses, topical Atorvastatin eye drop (50 µM) will be administered to the treatment eye at a dosage of one drop four times a day."

Category

Treatment - Drugs

2

Description

Control group: In the control group, only one affected eye of each patient will be included to receive the placebo. In addition to routine treatment, including eyelid hygiene, a topical placebo drop identical in appearance and composition to the intervention drop but without the active ingredient atorvastatin will be administered to the study eye, one drop four times daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Labbafinejad Medical Center

Full name of responsible person
Kiana Hassanpour Rahimabadi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Salar Bahrami

Position
Ophthalmology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available