Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the Efficacy of Topical Cyclosporine versus Flucort in Patients with Meibomian Gland Dysfunction: A Randomized Clinical Trial.Results

Protocol summary

Study aim

To compare the efficacy of topical cyclosporine, Fluocort, and artificial tears in the treatment of patients with meibomian gland dysfunction (MGD) and mild to moderate dry eye symptoms.

Design

A randomized, controlled, parallel-group clinical trial with assessor blinding will be conducted on 90 patients (30 per group). Patients will be randomly allocated to three groups: cyclosporine, Fluocort, and artificial tears (control). Randomization will be performed using a random number table.

Settings and conduct

The study was conducted at Torfeh Eye Hospital in Tehran. Ninety eligible patients were randomly assigned to three groups. Treatment efficacy was assessed using clinical dry-eye parameters. Patients were not blinded, while the outcome assessor was blinded to treatment allocation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria Patients aged over 18 years. Patients diagnosed with meibomian gland dysfunction (MGD) with mild to moderate dry eye symptoms. Exclusion Criteria Withdrawal of consent or unwillingness to continue participation in the study. Development of drug hypersensitivity or allergy. Schirmer test result of less than 10 mm over 5 minutes and tear meniscus height of less than 1 mm. History of ocular surgery. History of hormonal medication use. History of contact lens use. History of systemic diseases such as hypertension or diabetes mellitus. Presence of blepharitis or treatment for blepharitis within the previous 3 months.

Intervention groups

Group 1: Cyclosporine topical cyclosporine eye drops every 12 hours. Group 2: Fluocort Fluocort eye drops every 12 hours. Group 3: Artificial Tears (Control Group) artificial tear eye drops every 6 hours. This group will serve as the control group.

Main outcome variables

OSDI score; Tear Break-Up Time (TBUT); Schirmer test; Tear meniscus height; Meibography;NIBUT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260517069427N1**
Registration date: **2026-10-14, 1405/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-14, 1405/07/22**
Update count: **0**

Registration date

2026-10-14, 1405/07/22

Registrant information

Name

Hossein Mohammad Ribei

Name of organization / entity

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the Efficacy of Topical Cyclosporine versus Flucort in Patients with Meibomian Gland Dysfunction: A Randomized Clinical Trial.Results

Public title
Comparing the Efficacy of Topical Cyclosporine versus Flucort in Patients with Meibomian Gland Dysfunction: A Randomized Clinical Trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
بیماران با سن بالای 18 سال مبتلا به اختلال عملکرد غدد میبومین با علائم خشکی چشم خفیف تا متوسط

Exclusion criteria:
Patients who are unwilling to continue participating in the research study Development of a drug hypersensitivity reaction Schirmer test result of less than 10 mm over 5 minutes and tear meniscus height of less than 1 mm History of ocular surgery History of hormonal medication use History of contact lens use History of systemic diseases such as hypertension or diabetes Presence of blepharitis or treatment for blepharitis within the past 3 months

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **30**
One eye from each participant will be included as the study sample. Only one eye will be evaluated for each participant, and the selected eye will be considered the unit of analysis.

Randomization (investigator's opinion)
Randomized

Randomization description
Unit of randomization: The unit of randomization in this study is the patient. Eligible patients will be randomly assigned to one of the three treatment groups. Method of sequence generation: The random allocation sequence will be generated using a random number table. After enrollment, each eligible patient will be assigned to one of the three treatment groups according to the predetermined randomization sequence. Allocation concealment: Due to the nature of the interventions, patients will be aware of their assigned treatment and therefore patient blinding will not be performed. However, the researcher/assessor responsible for evaluating and recording the study outcomes will be blinded to the treatment allocation. Patient assignment will be performed according to the randomization table, and the outcome assessor will not be informed of the patients' treatment groups.

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 Shahid Beheshti University of Medical Sciences

Street address
Baharestan District, Ibn Sina Street, Torfeh Eye Hospital, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
4751411498

Approval date
2026-08-27, 1405/06/05

Ethics committee reference number
IR.SBMU.MSP.REC.1405.065

Health conditions studied

1

Description of health condition studied
Meibomian Gland Dysfunction (MGD)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Improvement in dry eye symptoms and signs

Timepoint
Assessment of dry eye symptoms and signs, including the Schirmer test and other clinical parameters, before the start of the study and one month after treatment.

Method of measurement
OSDI, Tear Break-Up Time(TBUT), Non-Invasive Tear Break-Up Time(NIBUT), Meibography, Schirmer Test, Ocular Surface Staining

Secondary outcomes

1

Description
Changes in Schirmer test; TBUT; NIBUT; corneal staining; meibomian gland area; OSDI score; meibomian gland morphology
Timepoint
One month after treatment, the tests and clinical examinations will be repeated for comparison.
Method of measurement
Schirmer test; Tear Break-Up Time (TBUT); Non-Invasive Tear Break-Up Time (NIBUT); corneal staining; meibomian gland area; OSDI score; changes in meibomian gland morphology

Intervention groups

1

Description
Intervention group: Cyclosporine 0.05% eye drops, one drop every 12 hours in both eyes for 1 months.
Category
Treatment - Drugs

2

Description
Intervention group: Fluocort 0.1% eye drops, one drop every 12 hours in both eyes for 1 month
Category
Treatment - Drugs

3

Description
Control group: Tearlose artificial tears, one drop every 6 hours in both eyes for 1 month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Torfeh Eye Hospital
Full name of responsible person
Hossin Mohamadrabi
Street address
Baharestan District, Ibn Sina Street, Torfeh Eye Hospital, Tehran, Iran
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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?
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
Iran University of Medical Sciences
Full name of responsible person
Hossin mohamad rabi
Position
Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified individual participant data, study protocol, statistical analysis plan, clinical study report, and data dictionary. The shared participant data will include deidentified clinical and outcome data collected during the study.
When the data will become available and for how long
The data and documents will become available 6 months after publication of the study results and will remain available for 5 years.
To whom data/document is available
The deidentified data and study documents will be available to academic researchers and other researchers with a legitimate scientific research purpose
Under which criteria data/document could be used
Data may be used for legitimate scientific research, secondary analyses, and systematic reviews. Requests will be reviewed by the research team, and data will only be provided after approval and confirmation of confidentiality.
From where data/document is obtainable
Requests should be submitted to the principal investigator via the contact information provided in the IRCT registration. Approved data and documents will be provided electronically.
What processes are involved for a request to access data/document
Applicants should submit a written request describing their research purpose and proposed analysis. Requests will be reviewed by the research team. Approved requests will be processed within 30 days.
Comments
تنها داده‌های غیرقابل شناسایی به اشتراک گذاشته خواهند شد و هیچ‌گونه اطلاعاتی که بتواند به‌طور مستقیم هویت شرکت‌کنندگان را مشخص کند ارائه نخواهد شد.