Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Effect of topical cyclosporin A in patients with dry eye referring to Ophthalmology Clinic of Vali-Asr Hospital in Birjand

Protocol summary

Summary

This study aims to investigate the effects of topical cyclosporin A on dry eye. A total of 30 patients will be selected from among those referred to the Ophthalmology Clinic of Vali-Asr Hospital in Birjand. The participants should be suffering from clinical and paraclinical symptoms of dry eye and be willing to participate in the study. Selection will be through purposive sampling method, and the study is single-blinded, one-centered, and in the third phase of clinical trial. The right eyes of the participants are considered as the case group and their left eyes, as the control group. One drop of cyclosporin A eye drop will be used for the right eye every 12 hours, and one drop of artificial tear eye drop will be applied every 12 hours for both eyes. The treatment will continue for 3 months. The subjective symptoms, as the primary outcomes of the study, will be examined in terms of duration, frequency, and severity on the first visiting session, one week, one month, and three months later. The signs include feeling eye dryness, feeling of sand in the eyes, itching, pain and burning eyes, watery eye, and eye fatigue.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016093030059N1**
Registration date: **2016-11-17, 1395/08/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-17, 1395/08/27

Registrant information

Name

Shabnam Ghavamahmadi

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 5252 3449

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2016-11-22, 1395/09/02

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical cyclosporin A in patients with dry eye referring to Ophthalmology Clinic of Vali-Asr Hospital in Birjand

Public title

Effect of cyclosporin on dry eye treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All visitors to the ophthalmology clinic of Valiasr Hospital of Birjand with clinical and paraclinical signs of dry eye; willingness to participate in the study; Non-occurrence of blindness in or conjunctivitis of one eye or both eyes; absence of foreign body in the eye; non-closure of the eye because of recent surgery, or non-

occurrence of dry eye after trauma or burning; Exclusion criteria: unwillingness to continue the study

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Birjand University of Medical Sciences

Street address
Ghaffari St.,

City
Birjand,

Postal code

Approval date
2016-05-23, 1395/03/03

Ethics committee reference number
Ir.bums.13950.10

Health conditions studied

1

Description of health condition studied
Dry Eye

ICD-10 code
H04.1

ICD-10 code description
Other disorders of lacrimal gland

Primary outcomes

1

Description
Dry eyes

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

2

Description
feeling of sand in the eyes

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

3

Description
itching

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

4

Description
pain and burning eyes

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

5

Description
watery eye

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

6

Description
eye fatigue

Timepoint
Before intervention, one week, one month, and three months after intervention

Method of measurement
Schirmer's test; SPEED scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The right eyes are considered as the intervention group in which one drop of cyclosporine A eye drop will be used every 12 hours for 3 months.
Category
Treatment - Drugs

2

Description
Control group: The left eyes are considered as the control group in which one drop of artificial eye drop will be used every 12 hours for 3 months. (It is noteworthy that that the same amount of drop will be used simultaneously in the intervention group as well.)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ophthalmology Clinic of Valiasr Hospital
Full name of responsible person
Shabnam Ghavamahmadi
Street address
Ophthalmology Clinic, Valiasr Hospital, Ghafari Street,
City
Birjand,

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research, Birjand University of Medical Sciences
Full name of responsible person
Toktam Sanjari
Street address
Birjand University of Medical Sciences, Ghafari Street,
City
Birjand,
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research, Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty