

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy and Safety of Ophthalmic Probiotic Lysate on Ocular Surface Microbiota, Immunological and Clinical Outcomes of Patients With Dry Eye Syndrome

Protocol summary

Study aim

Efficacy and Safety of Ophthalmic Probiotic Lysate on Ocular Surface Microbiota, Immunological and Clinical Outcomes of Patients With Dry Eye Syndrome

Design

Two arm randomized parallel equal groups with blinded care and outcome assessment

Settings and conduct

Patients with dry eye syndrome attended Shiraz University of Medical Sciences ophthalmology clinic will be enrolled in the study and patient allocation, follow up and outcome evaluation will be blinded

Participants/Inclusion and exclusion criteria

Inclusion of Male or Female, 18<age<60, vision>=9/10
Exclusion of patients with any underlying diseases or ocular surgery

Intervention groups

Intervention group: ophthalmic probiotic drop, 1 drop Q6h, for 4 weeks
Control group: ophthalmic placebo drop, 1 drop Q6h, for 4 weeks

Main outcome variables

Ocular Surface Microbiota, Immunological and Clinical Outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110811007297N8**
Registration date: **2022-05-22, 1401/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

Registration date

2022-05-22, 1401/03/01

Registrant information

Name

Mojtaba Heydari

Name of organization / entity

Shiraz university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Ophthalmic Probiotic Lysate on Ocular Surface Microbiota, Immunological and Clinical Outcomes of Patients With Dry Eye Syndrome

Public title

Efficacy and Safety of Ophthalmic Probiotic Lysate on Ocular Surface of Patients With Dry Eye Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or Female 18<age<60 Best corrected vision>=9/10

Signed informed consent Voluntary adherence to treatment

Exclusion criteria:

Pregnancy/breastfeeding Conjunctivitis Thyroid disease Diabetes Rheumatologic diseases including Sjogren's syndrome Neurologic conditions, including stroke, Bell's palsy, Parkinson's, trigeminal nerve problem Refractive surgery (LASIK or PRK) Other Eye Surgeries HSV Keratitis Medication/supplement use, including psychiatric medicines, OTC cold medicines, anti-histamines, beta-blockers, pain relievers, sleeping pills, diuretics, Hormones replacement, and oral contraceptives Chemical splashes / injuries to the eyes Contact lens use Environmental (dusty, windy, hot/dry) Any treatment for dry eye in previous 4 weeks (including lubricants, steroids, cyclosporine)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **1**

Tear sample for Schirmer, Interleukin and microbiom analysis

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization list will be generated by Excel software. Each eye will be randomly assigned to the active drug or placebo according to the randomization list.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding of the patients will be achieved by the similarity of drug and placebo. Blinding of the outcome assessor will be achieved by not disclosing patients allocation group to the assessor. Blinding of the statistician will be achieved by not disclosing data groups to him.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shiraz University of Medical Sciences

Street address

No. 16, Zand Blvd., Shiraz

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Province

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Postal code

71348-14336

Approval date

2021-07-05, 1400/04/14

Ethics committee reference number

IR.SUMS.REC.1400.343

Health conditions studied

1

Description of health condition studied

Dry eye syndrome

ICD-10 code

H04. 12

ICD-10 code description

dry eye syndrome

Primary outcomes

1

Description

Ocular Surface Disease Index

Timepoint

4 weeks

Method of measurement

questionnaire

2

Description

Tear break up time (TBUT)

Timepoint

4 weeks

Method of measurement

Slit exam with fluorescein staining

3

Description

Schirmer test

Timepoint

4 weeks

Method of measurement

Physical exam with Schirmer strip

4

Description

Ocular surface microbiota composition

Timepoint

4 weeks

Method of measurement

Measured by 16s rRNA method

5**Description**

Tear Interleukin level

Timepoint

4 weeks

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: ophthalmic probiotic drop, 1 drop Q6h, for 4 weeks

Category

Treatment - Drugs

2**Description**

Control group: ophthalmic placebo drop, 1 drop Q6h, for 4 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ophthalmology Clinic, Shiraz University of Medical Sciences

Full name of responsible person

Mojtaba Heydari

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Mojtaba Heydari

Position

clinician scientist

Latest degree

Ph.D.

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Full name of responsible person
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Medical Biotechnology

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Web page address

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