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)
Phone
+98 71 1235 7679
Email address
mheydari@sums.ac.ir

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

City

Shiraz

Province

Fars

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
Street address
Shiraz University of Medical Sciences, Zand St. Shiraz
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3212 2884
Email
gsia@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abbas Rezaianzadeh
Street address
Vice chancellor for research, Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3212 2430
Email
rezaiana@sums.ac.ir
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
Street address
No. 16, Zand Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 1235 7679
Fax

Email
mheydari@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
No. 16, Zand Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 1235 7679
Fax
Email
ghasemiy@sums.ac.ir

Person responsible for updating data

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
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7135744661
Phone
+98 71 1233 6541
Fax
+98 71 1233 6541
Email
mheydari@sums.ac.ir
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