

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Examining the health and effectiveness of using exosomes derived from limbal mesenchymal stem cells in dry eye patients

Protocol summary

Study aim

Examining the health and effectiveness of using exosomes derived from limbal mesenchymal stem cells in dry eye patients

Design

Clinical trial, parallel groups, blind on one side, phase 3 on 30 patients.

Settings and conduct

In this research, all patients with complaints of burning or itching or feeling of a foreign body in the eye, referred to Rasoul Akram Hospitals in Tehran, will be included in the study. The sample size is 30 people. A total of 40 patients will be examined. Data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with complaints of burning or itching or feeling of a foreign body in the eye, Moderate and severe dry eye severity, Age between 18-70 years. Exclusion criteria: Previous history of eye surgery, Any disease that suppresses the immune system, Pregnancy and breastfeeding, Eyelid abnormalities, Use of eye drops in the past year except artificial tears and lubricating ointments, Use of systemic drugs that affect the tear film in last three months, Use of systemic steroid in the last three months, Use of contact lenses in the last three months

Intervention groups

Intervention group: Patients will receive one drop (0.05 cc) of exosome with one drop (0.05 cc) of artificial tears without preservative in the right eye, every 6 hours (4 times a day) for three months. Control group: Patients will receive one drop (0.05 cc) of artificial tears without preservative in the left eye, every 6 hours (4 times a day) for three months.

Main outcome variables

Dry eye

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059814N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Kian Alirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

kian.alirezaei.72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the health and effectiveness of using exosomes derived from limbal mesenchymal stem cells in dry eye patients

Public title

The effect of exosomes on dry eye

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with complaints of burning or itching or feeling of a foreign body in the eye Moderate and severe dry eye severity Age between 18-70 years

Exclusion criteria:

Previous history of eye surgery Any disease that suppresses the immune system Pregnancy and breastfeeding Eyelid abnormalities Use of eye drops in the past year except artificial tears and lubricating ointments Use of systemic drugs that affect the tear film in last three months Use of systemic steroid in the last three months Use of contact lenses in the last three months

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each of the participants, the right eye and the left eye will be examined as 2 samples. The intervention will be done in the right eye and the left eye will be the intervention group.

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-09-12, 1402/06/21

Ethics committee reference number

IR.IUMS.FMD.REC.1402.283

Health conditions studied

1

Description of health condition studied

Dry eye

ICD-10 code

H04.12

ICD-10 code description

Dry eye syndrome

Primary outcomes

1

Description

Dry eye

Timepoint

Before the intervention, 4 and 12 weeks after the intervention

Method of measurement

Based on the ocular surface disease index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with dry eyes, will receive in the right eye, one drop (0.05 cc) of exosome derived from limbal mesenchymal stem cells with a concentration of 0.01 micro liter (produced in the laboratory by the researcher) along with one drop (0.05 cc) artificial tears Advanced 0.15 without preservative containing 150 mg of sodium hyaluronate per 100 ml (manufacturer: Artipic Pharmaceutical Company), every 6 hours (4 times a day) for three months.

Category

Treatment - Drugs

2

Description

Control group: Patients with dry eyes, will receive in the left eye, one drop (0.05 cc) artificial tears Advanced 0.15 without preservative containing 150 mg of sodium hyaluronate per 100 ml (manufacturer: Artipic Pharmaceutical Company), every 6 hours (4 times a day) for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-Akram Hospital

Full name of responsible person

Kian Alirezaei

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

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Rasoolhospital@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

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research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Hossein Aghaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hossein Aghaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Email

Kian.alirezai.72@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Kian Alirezai

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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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