

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Investigating the therapeutic effect of eye drops obtained from Wharton's jelly stem cell exosomes in patients with severe dry eyes

Protocol summary

Study aim

To evaluate the safety and initial efficacy of exosome eye drops isolated from Wharton's jelly mesenchymal stem cells (MSC-Exo) in the treatment of dry eye diseases.

Design

The current study is a non-random, single arm, before and after intervention study with 30 people who suffering from dry eye diseases. Patients referred to the vision health clinic who meet the criteria for the study will be included in the study.

Settings and conduct

This study will conducted in the vision health clinic at Semnan University of Medical Sciences. Thirty patients with dry eye diseases will participate after normalization with artificial tears. Eye drops contain exosomes derived from stem cells in two eyes, four times daily for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clinical diagnosis of dry eye symptoms by ophthalmologists; These symptoms must be present in at least one eye: dryness, burning sensation, foreign body sensation, eye surface discomfort or visual fatigue; Tear secretion test (Schirmer test) both eyes ≤ 10 mm / 5 minutes. Exclusion exclusion: being allergic to any of the drug components; Pregnant or lactating women; Patients with active fungal, bacterial or viral keratitis or conjunctivitis; suffering from serious heart, lung, liver or kidney diseases; other incurable eye diseases before the study Such as glaucoma, uveitis, retinitis pigmentosa

Intervention groups

Intervention: Administration of eye drops containing exosome of stem cells, 4 drops per day for 3 months in patients with severe dry eyes

Main outcome variables

The percentage of patients with increasing of Tear Film Break-up Time; Ocular Surface Staining

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170211032503N2**

Registration date: **2024-02-20, 1402/12/01**

Registration timing: **prospective**

Last update: **2024-02-20, 1402/12/01**

Update count: **0**

Registration date

2024-02-20, 1402/12/01

Registrant information

Name

Hossein Aghamollaei

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-29, 1403/02/10

Expected recruitment end date

2024-12-30, 1403/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the therapeutic effect of eye drops obtained from Wharton's jelly stem cell exosomes in patients with severe dry eyes

Public title

Using exosome to treat severe dry eyes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with severe dry eye based on symptoms in at least one eye: dryness, burning sensation, foreign body sensation, discomfort in the ocular surface or visual fatigue Failure to respond to routine treatments Tear secretion test (Schirmer test) both eyes ≤ 10 mm / 5 minutes.

Exclusion criteria:

Those who are allergic to any of the drug components in this study. Pregnant or lactating women Patients with active fungal, bacterial or viral keratitis or conjunctivitis Suffering from serious heart, lung, liver, or kidney diseases; Patients with Diabetes

Age

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

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Headquarters of Semnan University of Medical Sciences, Basij Blvd.

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2024-01-01, 1402/10/11

Ethics committee reference number

IR.SEMUMS.REC.1402.235

Health conditions studied

1

Description of health condition studied

Severe dry eye

ICD-10 code

H04.129

ICD-10 code description

Dry eye syndrome of unspecified lacrimal gland

Primary outcomes

1

Description

The percentage of patients with increasing of Tear Film Break-up Time

Timepoint

Before intervention, one week, 4 weeks and 12 weeks after intervention

Method of measurement

The time required for dry spots to appear on the surface of the eye after blinking is in seconds. A positive change from baseline indicates improvement in each eye.

2

Description

Ocular Surface Staining

Timepoint

Before intervention, one week, 4 weeks and 12 weeks after intervention

Method of measurement

An area of the cornea that is stained with fluorescein dye and it will be assessed using a slate lamp microscope. Ocular surface damage will be measured by slit lamp examination after staining with non-toxic sodium fluorescein. Corneal and conjunctival staining will be graded based on the National Eye Institute (NEI) imaging scale. The lower the score has the less dry eye symptoms the patient. A negative change from baseline indicates improvement in each eye.

3

Description

The volume of tear

Timepoint

Before intervention, one week, 4 weeks and 12 weeks after intervention

Method of measurement

A paper strip is placed on the eye under the lower eyelid

for a certain period of time. The length of the tear-soaked strip will be measured in millimeters. A positive change from baseline indicates improvement in each eye.

Secondary outcomes

1

Description

Uncorrected visual acuity

Timepoint

Before intervention, 1week, 1 month and 3 months after intervention

Method of measurement

Measurement of vision based on Snellen chart

2

Description

Best corrected visual acuity

Timepoint

Before intervention, 1week, 1 month and 3 months after intervention

Method of measurement

Measurement of vision based on Snellen chart

Intervention groups

1

Description

Intervention Group: A group of 30 individuals diagnosed with dry eye disease which will referred to the Vision Health Clinic will enrolled in the study. The medication consists of eye drops containing stem cell-derived exosomes, which the patient will instill into their eyes four times a day for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vision Health Research Center

Full name of responsible person

Hossein Aghamolaei

Street address

Unit 17, 5th floor, No. 8, Second Alley, Vali Asr Street

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vision health research center

Full name of responsible person

Khosrow Jadidi

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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

This study will not have any other financial source

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Vision health research center

Full name of responsible person

Hossein Aghamolaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical biotechnology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Vision health research center

Full name of responsible person

Khosrow Jadidi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

Contact

Name of organization / entity

Vision Health Research Center

Full name of responsible person

Mahsa Fallah Tafti

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Research Assistant

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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

All the results obtained based on the disease improvement process along with the age and sex of the patient will be available.

When the data will become available and for how long

All the results obtained based on the disease improvement process along with the age and sex of the patient will be available after the completion of the three-month follow-up period.

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

In the case of obtaining permission from experts, the relevant applicants can access the data at the designated time. Only encrypted data and no personal patient profiles will be accessible.

From where data/document is obtainable

The email address along with the contact number of the respondents will be provided to the applicants

What processes are involved for a request to access data/document

After the completion of the three-month treatment period, after receiving an email from the applicant, the documents will be provided to the applicant.

Comments