Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effect of human umbilical cord Whartons jelly-derived Mesenchymal stem cells exosomes in treatment of Dry Eye Related to Graft-Versus-Host Disease

Protocol summary

Study aim

The effect of human umbilical cord Wharton jelly-derived mesenchymal stem cell exosomes in the treatment of dry eye in graft-versus-host disease.

Design

The phase I, parallel-design, interventional clinical trial will be conducted on 10 non-randomly selected patients with dry eye disease and graft-versus-host disease. After enrollment, the patient's right eye will be treated with exosome. The left eye will be treated with placebo as a control.

Settings and conduct

This study is carried out in the Khalili therapeutic training center. First, the exosome is isolated from the mesenchymal stem cells of the Wharton's jelly of the umbilical cord and is made into eye drops. Then, the drop containing exosome is treated twice a day for 14 days for the patient's right eye and the left eye with placebo.

Participants/Inclusion and exclusion criteria

Patients with Graft-versus-host disease between 30-60 years old, suffering from dry eye that the previous use of artificial tears could not remove the symptoms of dry eye and at least in one eye the symptoms of eye redness, dryness, burning sensation, foreign body sensation, discomfort at the level of the eye or have vision fatigue and the tear secretion test of both eyes is less than 10 mm in 5 minutes and the tear break time is less than 10 seconds and the degree of fluorescein staining of the cornea is more than 4. No entry: people with drug sensitivity, pregnant or lactating women, patients with serious heart, lung, liver or kidney diseases or other incurable eye diseases.

Intervention groups

The intervention group will consist of the right eyes of ten patients with graft-versus-host disease who have failed routine dry eye treatments and will be treated with exosome, while the control group will consist of a placebo in the left eye of the subjects.

Main outcome variables

Increasing tear secretion and reducing dry eye manifestations

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240508061704N3**
Registration date: **2025-05-10, 1404/02/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-10, 1404/02/20**
Update count: **0**

Registration date

2025-05-10, 1404/02/20

Registrant information

Name

Somayeh Keshtkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 5592

Email address

somayehkeshtkar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-05, 1403/09/15

Expected recruitment end date

2025-09-06, 1404/06/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of human umbilical cord Whartons jelly-derived Mesenchymal stem cells exosomes in treatment of Dry Eye Related to Graft-Versus-Host Disease

Public title
The effect of stem cell secretions isolated from the newborn's umbilical cord in the treatment of dry eye manifestations and tear secretion in patients with transplant versus host disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients between 30-60 years old who have dry eyes and have been clinically and serologically diagnosed with GVHD by an ophthalmologist and hematologist Patients in whom the previous use of artificial tears could not relieve the symptoms of dry eyes Patients who have symptoms of eye redness, dryness, burning sensation, foreign body sensation, eye surface discomfort or visual fatigue in at least one eye Patients whose tear secretion test in both eyes is ≤ 10 mm / 5 minutes and tear break time is less than 10 seconds and the degree of corneal fluorescein staining is more than 4.
Exclusion criteria:
People who are allergic to any medicine Pregnant or lactating women Patients with active fungal, bacterial or viral keratitis or conjunctivitis People who have serious heart, lung, liver or kidney or systemic diseases Patients who have incurable eye diseases before the study; Such as glaucoma, uveitis People who use contact lenses and do not want to remove them in the study People who have had eye surgery (including cataract surgery) in the last three months People who have simultaneously enrolled in other interventional clinical studies People who have used eye drops that may affect the clinical study in the last 24 hours.
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz - Zand Street - Shiraz University of Medical Sciences central building
City
Shiraz
Province
Fars
Postal code
۷۱۹۳۶۳۵۸۹۹
Approval date
2024-02-17, 1402/11/28
Ethics committee reference number
IR.SUMS.REC.1402.588

Health conditions studied

1

Description of health condition studied
Dry eye in GVHD disease
ICD-10 code
T86.0
ICD-10 code description
Complications of bone marrow transplant

Primary outcomes

1

Description
Tear secretion is measured using the Schirmer test, which measures the amount of wetting of filter paper.
Timepoint
Measurements are taken before the start of treatment and after 12 weeks.
Method of measurement
Filter paper is placed next to the eye and the amount of wetting by tears is reported in millimeters.

Secondary outcomes

1

Description

The amount of change in the height of the tear meniscus is measured.

Timepoint

Measurements are taken before the start of treatment and after 12 weeks.

Method of measurement

Imaging is performed with a slit lamp device.

2

Description

The detection of foreign bodies in the eye is measured using fluorescein orange and blue light.

Timepoint

Measurements are taken before the start of treatment and after 12 weeks.

Method of measurement

Number

Intervention groups

1

Description

Intervention group: First, exosomes isolated from umbilical cord Wharton's jelly mesenchymal stem cells are isolated and stored in phosphate buffered saline (PBS) in a freezer. After admission, the patient's right eye will be treated with exosome as the intervention group. First, artificial tears will be injected into the right eye for 2 weeks until the baseline level is normalized, and then the intervention will be performed in the form of 10 micrograms of exosomes per drop, twice a day for 14 days in one eye of the patient.

Category

Treatment - Other

2

Description

Control group: After taking the patient, the patient's left eye will be considered as a control. PBS buffer alone will be used for the control eye.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Medical Education Center

Full name of responsible person

Dr. Amir Khosravi

Street address

Shiraz - Mollasadra St. - Khalili St. - Khalili Medical Education Center

City

Shiraz

Province

Fars

Postal code

7193616641

Phone

+98 71 3629 1495

Email

amir11khosravi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Hashem Hashempour

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3235 7282

Email

vcrdep@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

Negar Azarpira

Position

Full professor

Latest degree

Specialist

Other areas of specialty/work

Pathology

Street address

Mulla Sadra St., Khalili St., Mohammad Rasoolullah Research Tower

City
Shiraz

Province
Fars

Postal code
۷۱۹۳۶۳۵۸۹۹

Phone
+98 71 3628 1407

Email
negarazarpira@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Negar Azarpira

Position
Full professor

Latest degree
Specialist

Other areas of specialty/work
Pathology

Street address
Mulla Sadra St., Khalili St., Mohammad Rasoolullah Research Tower

City
Shiraz

Province
Fars

Postal code
۷۱۹۳۶۳۵۸۹۹

Phone
+98 71 3628 1407

Email
negarazarpira@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Somayeh Keshtkar

Position
Laboratory expert

Latest degree
Ph.D.

Other areas of specialty/work
Molecular medicine

Street address
Molecular Dermatology Research Center Shahid Faghihi hospital, Zand Avenue,

City
Shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3212 5592

Email
somayehkeshtkar@gmail.com

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
Demographic characteristics from the results of a project to investigate effect of human umbilical cord Whartons jelly-derived Mesenchymal stem cells exosomes in treatment of Dry Eye Related to Graft-Versus-Host Disease

When the data will become available and for how long
Immediately after the publication of the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
Send researchers' requests via email and make a commitment to applicants to protect the data

From where data/document is obtainable
Sending researchers' requests via e-mail to the e-mail address of the executor and in charge of the project, Dr. Negar Azarpira- negarazarpira@gmail.com

What processes are involved for a request to access data/document
The applicant researcher has sent his request to the email address of the executive and project manager, Dr.Negar Azarpira, to the email address of negarazarpira@gmail.com. After reviewing it within a week, after receiving a commitment, the data will be sent to the applicant via email.

Comments