Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of human umbilical cord Wharton’s jelly-derived Mesenchymal stem cells exosomes in treatment of dry eye disease in primary sjogren’s syndrome

Protocol summary

Study aim
The effect of Wharton jelly-derived mesenchymal stem cell exosomes on the treatment of dry eye in primary sjögren’s syndrome.

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 2-1 on 5 patients. Excel software rand function will be used for randomization.

Settings and conduct
In the dermatology ophthalmology clinic, 5 patients with sjögren’s syndrome will be admitted, then artificial tears will be injected for 2 weeks, then in the treated eye, the exosome containing eye drops will be used twice a day for 14 days and will be followed up for 12 weeks. Blinding will be performed in triple blindness and in three groups of patients, researcher and data analyzer.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Women 35-35 years old with dry eye sjögren’s syndrome, no relief with artificial tears, ocular manifestations, tear secretion test ≤ 10 mm and tear break time less than 10 seconds. Exclusion criteria: People with drug allergies, pregnant or lactating women, incurable eye diseases or other serious systemic diseases, people with contact lenses, eye surgery in the last three months, attending other studies or using other eye drops.

Intervention groups
One eye as treatment and the other eye as control. Warton jelly-derived mesenchymal stem cell exosomes will be used in the treated eye and normal sillin in the control eye.

Main outcome variables
Evaluation of dry eye; Tear secretion; Symptoms of dry eye include Ocular Surface Disease Index, Tear meniscus thickness, Tear film break-up time, Fluorescein corneal staining test and Schirmer I test.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211102052948N1**
Registration date: **2022-04-20, 1401/01/31**
Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**
Update count: **0**

Registration date
2022-04-20, 1401/01/31

Registrant information

Name
Azam Habibi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of human umbilical cord Wharton’s jelly-derived Mesenchymal stem cells exosomes in treatment of dry eye disease in primary sjogren’s syndrome

Public title
Evaluation of the exosome effect of Wharton jelly mesenchymal stem cells in the treatment of dry eye

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Middle-aged women between the ages of 45 and 35 with dry eye Clinically and serologically diagnosed by an ophthalmologist, rheumatologist or internal medicine specialist with sjogren’s syndrome. Previous use of artificial tears can not relieve it. Symptoms of dry eye in at least one patient's eye include redness, dryness, burning sensation, foreign body sensation, eye discomfort, or visual fatigue. Tear discharge test (Schermer test) both eyes ≤ 10 mm / 5 min Tear break time (TBUT) will be less than 10 seconds.

Exclusion criteria:
People who are allergic to any drug . Pregnant or lactating women . Patients with active fungal, bacterial or viral keratitis or conjunctivitis. People with serious heart, lung, liver or kidney disease or other incurable eye diseases such as glaucoma, uveitis. People who wear contact lenses and do not want to remove them in the study. Perform eye surgery (including cataract surgery) in the last three months. Simultaneous enrollment in other interventional clinical trials. Use of eye drops in the last 24 hours that may affect the clinical study. They have serious systemic diseases.

Age
From **35 years** old to **45 years** old

Gender
Female

Phase
1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **5**
More than 1 sample in each individual
Number of samples in each individual: **2**
In this study, one eye of each patient will be used as a control and the other eye as a treatment.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we have two blocks, A and B. Block A is such that the patient's right eye is treated with exosome and the left eye is controlled and B block :The left eye is treated with exosome and the patient's right eye is treated Control is considered. Each time the dice are thrown, if 1, 3 and 5 come, it will be block A, and if 2, 4 and 6 come, it will be block B, and because there is a sixth chance for each person each time, it will be random. Block A: Left eye:control Right eye : Intervention Block B: Right eye:control Left eye : Intervention

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this three-blind study, two vials of eye drops are given to the patient, one with code A and one with code B. And only the supervisor knows which vial contains stem cell exosomes. But the researcher, patient, and clinical data analyzer are unaware of which patient's eye's eye drop contains stem cell exosomes.

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
The central building of Shiraz University of Medical Sciences ., in front of Palestine Ave ., Zand Ave., Shiraz .

City
Shiraz

Province
Fars

Postal code
7194685791

Approval date
2022-02-28, 1400/12/09

Ethics committee reference number
IR.SUMS.REC.1400.852

Health conditions studied

1

Description of health condition studied
Dry eye due to Sjogren's syndrome

ICD-10 code
M35.0

ICD-10 code description
Sicca syndrome [Sjogren]

Primary outcomes

1

Description
Ocular Surface Disease Index (OSDI) Score

Timepoint

Before the intervention and in the Time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

A valid questionnaire is 12 questions that will be used to measure the symptoms of dry eye.

Secondary outcomes

1

Description

Changes in tear secretion amount

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

Schirmer's Test

2

Description

Changes in Tear break time

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

The time required for dry spots to appear on the surface of the eye after blinking will be measured in seconds.

3

Description

Changes in Ocular Surface Staining

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

Damage to the surface of the eye will be assessed using non-toxic eye dye during the slit lamp examination.

4

Description

Changes in conjunctiva redness score

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

Conjunctival hyperemia will be graded separately in each eye by the researcher assigning a score of 0 to 4 per quarter.

5

Description

Changes in tear meniscus thickness

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

The distance between the line of reflection along the top of the tear prism to the edge of the eyelid will be measured in millimeters.

6

Description

Evaluation of MMP9, EGF gene expression in tear secretions

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

RT-PCR technique

7

Description

Evaluation of MMP9 and EGF proteins in tear secretions

Timepoint

Before the intervention and in the time Frame: 1 week, 2 weeks, 3 weeks, 4 weeks, 6 weeks, 8 weeks, 10 weeks, 12 weeks after the intervention

Method of measurement

ELISA technique

Intervention groups

1

Description

Intervention group: Wharton jelly mesenchymal stem cell-derived exosomes. Participants will receive artificial tears for 2 weeks to return to normal, then WJMSC-exo 10ug / drop, four times a day for 14 days. The next visit will be 12 weeks later.

Category

Treatment - Other

2

Description

Control group: placebo containing phosphate buffered saline. Participants will receive artificial tears for 2 weeks to return to normal and then 10ug / drop of placebo containing phosphate buffered saline in each drop, four times a day for 14 days. The next visit will be 12 weeks later.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poustachi Ophthalmology Training Clinic

Full name of responsible person
Dr. Mahmoud Nejabat
Street address
beginning of Asadabadi Ave , in front of the Medical School , Zand Blvd , Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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The central building of Shiraz University of Medical Sciences , in front of Palestine Ave , Zand Blvd , Shiraz.
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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
Azam Habibi
Position
student
Latest degree
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Person responsible for updating data

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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 data related to the project and participants can be shared anonymously after the end of the study.
When the data will become available and for how long
Start of access period 6 months after publication of study results
To whom data/document is available
Faculty members of academic centers and researchers working in academic and scientific institutions
Under which criteria data/document could be used
Systematic review studies and meta-analysis
From where data/document is obtainable
Contact the scientific manager of the project
What processes are involved for a request to access data/document
Upon formal written request
Comments