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)

Phone

+98 21 8248 2260

Email address

abrcl@bmsu.ac.ir

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 Smenan 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
City
Tehran
Province
Tehran
Postal code
1516747418
Phone
+98 912 279 3682
Email
aghamolaei22@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vision health research center
Full name of responsible person
Khosrow Jadidi
Street address
Unit 17, 5th floor, No. 8, Second Alley, Vali Asr Street
City
Tehran
Province
Tehran
Postal code
1516747418
Phone
+98 912 105 3475
Email
kh.jadidi@gmail.com
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 Aghamollaei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical biotechnology
Street address
Unit 17, 5th floor, No. 8, Second Alley, Vali Asr Street
City
Tehran
Province
Tehran
Postal code
1516747418
Phone

+98 21 8819 6862

Email

aghamolaei22@gmail.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1516747418

Phone

+98 21 8819 6862

Email

kh.jadidi@gmail.com

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

Street address

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

City

تهران

Province

Tehran

Postal code

1516747418

Phone

+98 21 8819 6862

Email

mahsafallah8@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

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