Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of exosomes with regenerative and anti-inflammatory potential derived from Wharton jelly mesenchymal stem cells on the treatment of corneal epithelial defects

Protocol summary

Study aim
Investigating the therapeutic potential of exosomes derived from Wharton jelly mesenchymal stem cells (MSCs-Exos) in patients with corneal epithelial defects.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 20 patients. We use different software such as (R or Python) for randomization

Settings and conduct
In sterile conditions, Wharton's jelly is separated and its mesenchymal cells are cultured. Finally, after stimulating the production of extracellular vesicles in closed conditions and in a sterile environment, ultracentrifugation will be used to separate the vesicles. After adding growth factors and cytokines and according to the protocol for 20 days, they will be used for the studied groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Male and female subjects 18 years and older. • People with PED for at least seven (7) days. • The defect may be of any size and must be measurable with a slit lamp. • In the researcher's opinion, CED is stable, that is, CED has not improved despite conventional treatments such as tear supplements and bandage contact lenses. • Primary corneal defects can be the result of injury, infection, disease, or eye surgery. Exit criteria: • Have any active eye infection (bacterial, viral, fungal, or protozoal) in the affected eye(s). • Patients who have received surgical treatment such as amniotic membrane transplantation or currently have an indication for surgical treatment. • Patients with eyelid abnormalities. • Patients with malignancy • Pregnant or breastfeeding patients

Intervention groups
intervention group, exosome-containing drops are used in people with corneal epithelial defects, and in the control group, normal treatment without the use of drops.

Main outcome variables
Improvement of epithelial defects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240706062337N1**
Registration date: **2024-10-10, 1403/07/19**
Registration timing: **prospective**

Last update: **2024-10-10, 1403/07/19**
Update count: **0**

Registration date
2024-10-10, 1403/07/19

Registrant information

Name
Fatemeh Sanie-Jahromi

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
2024-12-17, 1403/09/27

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of exosomes with regenerative and anti-inflammatory potential derived from Wharton jelly mesenchymal stem cells on the treatment of corneal epithelial defects

Public title

Investigating the safety and efficacy of Wharton's jelly mesenchymal stem cell exosomes on corneal epithelium defects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants aged 18-65 years. Individuals diagnosed with corneal epithelial defects, confirmed by clinical examination and imaging techniques. Patients with moderate to severe corneal epithelial defects that have not responded to conventional treatments. Participants should be generally healthy, without systemic diseases that could affect the study outcomes. Written informed consent obtained from all participants. Patients who have not received any other experimental treatments for corneal epithelial defects in the past 6 months. No active ocular infections or other significant ocular diseases (e.g., glaucoma, uveitis) that could interfere with the study. Willingness and ability to comply with study procedures and follow-up visits.

Exclusion criteria:

Patients with uncontrolled systemic diseases such as diabetes, autoimmune disorders, or severe cardiovascular conditions. Presence of other significant ocular diseases (e.g., glaucoma, uveitis) or active ocular infections that could interfere with the study outcomes. Patients who have received other experimental treatments for corneal epithelial defects within the past 6 months. Known allergies to any components of the exosome preparation or related substances. Pregnant or breastfeeding women. Patients currently undergoing immunosuppressive therapy or with a history of organ transplantation. Inability or unwillingness to comply with study procedures and follow-up visits. Any other medical condition that, in the opinion of the investigator, could compromise the safety of the patient or the integrity of the study data.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

To create a random sequence, we use numbers to assign to participants using random functions in different software such as R or Python. We use the clinical characteristics of the patients to limit, and the division into groups is done based on the initial clinical condition of the person

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, double blinding was used to reduce the errors and conscious or unconscious effects of the researchers in measuring the outcomes. In this way, both patients and all researchers related to patients are unaware of the treatment received by the patient. Considering that this is a single-center study, by using a code, the patient is identified whether he received the active drug or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Zand St., in front of Palestine St.

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Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2024-07-08, 1403/04/18

Ethics committee reference number

IR.SUMS.REC.1403.123

Health conditions studied

1

Description of health condition studied

Corneal epithelium defects

ICD-10 code

H18.9

ICD-10 code description

Disorder of cornea, unspecified

Primary outcomes

1

Description
Improvement of epithelial defects
Timepoint
It is measured in weeks 1, 2 and 4
Method of measurement
Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group : Description: Patients will receive exosomes derived from Wharton jelly mesenchymal stem cells (WJ-MSCs) with regenerative and anti-inflammatory potential. Exosomes are prepared in the cleanroom of the University of Medical Sciences. Dosage and administration: Exosomes are prepared as 10% dilution with tearlose and packaged in eye drops. The drops are prescribed topically on the affected eye(s) once a day for 4 weeks. Objective: To evaluate the efficiency of exosomes derived from WJ-MSC in improving corneal epithelial healing and reducing inflammation.
Intervention group 2: Description: Patients will receive a standard treatment for corneal epithelial defects, such as tearlose artificial tears or conventional anti-inflammatory eye drops. Dosage and Administration: Standard treatment is performed according to usual clinical guidelines. Objective: To compare the effectiveness of standard treatment with exosome treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
POOSTCHI EYE CLINIC
Full name of responsible person
Fatima Sani Jahromi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Grant name
Vice Chancellor for Research, Shiraz University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, 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
Mahmoud Nejabat
Position
Professor
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available