Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of exosome-containing eyedrops efficacy on corneal epithelium repair after trans-PRK surgery in Baqiyatallah hospital: A randomized clinical trial

Protocol summary

Study aim
To evaluate the effect of umbilical cord–derived exosome eye drops on corneal epithelial healing and clinical outcomes after PRK.

Design
Randomized, double-blind, paired-eye clinical trial. For each patient, one eye is randomly assigned to intervention and the fellow eye to control using random numbers with sealed envelopes.

Settings and conduct
Patients referring to the ophthalmology clinic of Baqiyatullah Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: PRK candidates ≥18 years old, with good general health, and willingness to participate. Exclusion criteria: Ocular comorbidities (keratoconus, severe dry eye, corneal scarring), systemic/ocular medications interfering with healing, history of ocular surgery, or

Intervention groups
Test eye: Exosome eye drops (1 drop every 4 h) + routine PRK medications and bandage lens. Control eye: BSS placebo drops in identical vials + routine medications and bandage lens.

Main outcome variables
Time to complete corneal epithelial closure, assessed with fluorescein staining and slit-lamp examination on postoperative days 1, 2, 5, and 7.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250822066953N1**
Registration date: **2025-09-05, 1404/06/14**
Registration timing: **prospective**
Last update: **2025-09-05, 1404/06/14**
Update count: **0**

Registration date
2025-09-05, 1404/06/14

Registrant information
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Ahmad Vahidi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of exosome-containing eyedrops efficacy on corneal epithelium repair after trans-PRK surgery in Baqiyatallah hospital: A randomized clinical trial

Public title
Evaluation of exosome-containing eyedrops efficacy on corneal epithelium repair after trans-PRK surgery in Baqiyatallah hospital: A randomized clinical trial

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Indication for PRK surgery Willingness to participate in the study (informed consent) No concurrent cataract No nasolacrimal duct obstruction No eyelid margin infections (blepharitis) No pterygium or other fibrovascular ocular surface diseases No retinal diseases or glaucoma No systemic diseases interfering with corneal epithelial healing, such as diabetes or malnutrition
Exclusion criteria:
Failure to return for follow-up appointments after surgery Postoperative corneal surface infections such as corneal ulcers Failure to use prescribed eye drops as directed
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
For each patient, it is randomly determined which eye (right or left) will be placed in the test or control group.
Randomization (investigator's opinion)
Randomized
Randomization description
For block randomization, each patient is considered as a block. For each patient, it is randomly determined which eye (right or left) will be in the test or control group. This is done by generating random numbers (e.g., a random number table). In this way, if the random number is even, the right eye will be the test and the left eye will be the control. If the random number is odd, the left eye will be the test and the right eye will be the control. A sealed envelope is prepared for each patient, inside which it is specified which eye will be in which group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is designed as a double-blind study, and the drops are pre-made by the manufacturer with a completely similar appearance and coded so that there is no difference between the exosome drops and the placebo drops, and neither the examiner nor the patient knows which eye the exosome drop was placed in and which artificial tear was placed in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Baqiyatullah Educational and Medical Center
Street address
Baqiyatallah Hospital, Sheikh Bahaii Street, Molla Sadra Street, Vanak Square
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Approval date
2025-08-05, 1404/05/14
Ethics committee reference number
IR.BMSU.REC.1404.016

Health conditions studied

1

Description of health condition studied
Myopia
ICD-10 code
H52.1
ICD-10 code description
Myopia

2

Description of health condition studied
Hypermetropia
ICD-10 code
H52.0
ICD-10 code description
Hypermetropia

3

Description of health condition studied
Astigmatism
ICD-10 code
H52.2
ICD-10 code description
Astigmatism

4

Description of health condition studied
Other specified postprocedural states
ICD-10 code
Z98.89
ICD-10 code description
Other specified postprocedural states

5

Description of health condition studied
Unspecified disorder of refraction
ICD-10 code
H52.7
ICD-10 code description
Unspecified disorder of refraction

Primary outcomes

1

Description
Time to complete corneal epithelial healing
Timepoint
Postoperative days 1, 2, 5, and 7 (until complete closure).
Method of measurement
Application of sterile fluorescein strip and cobalt blue illumination under slit-lamp.Measurement of defect size (length × width in mm) using slit-lamp graticule.Recording of “complete/not complete closure” and calculation of time (days) to full re-epithelialization.

Secondary outcomes

1

Description
Early ocular surface healing and symptoms(Corneal epithelial defect size,Conjunctival injection (redness),Pain score)
Timepoint
Days 1, 2, 5, and 7.
Method of measurement
Fluorescein staining under slit-lamp; measurement with calibrated graticule (mm² or length × width).Standard grading based on the American Academy of Ophthalmology reference chart.Visual Analog Scale (VAS 0–10) recorded in the checklist.

2

Description
Corneal clarity and visual acuity
Timepoint
Months 1, 3, and 6.
Method of measurement
Standard slit-lamp haze grading; documented in questionnaire.Snellen or LogMAR chart.

3

Description
Dry eye assessment
Timepoint
Months 1, 3, and 6.
Method of measurement
Fluorescein dye instillation, cobalt blue slit-lamp; time (seconds) until first dry spot appears.Sterile strip placed in lower fornix; length of wetting (mm) after standard duration.Clinical evaluation with slit-lamp; recorded in mm.

Intervention groups

1

Description
Intervention group(Exosome):Treatment: Topical exosome eye drops derived from human umbilical cord mesenchymal stem cells (Arotamin company).Dose/Frequency: One drop every 4 hours.Notes: Provided in masked, identical vials; patients also receive standard PRK postoperative medications and bandage contact lens.
Category
Treatment - Drugs

2

Description
Control group: Treatment: Balanced Salt Solution (BSS) placebo eye drops in identical, masked vials.Dose/Frequency: One drop every 4 hours.Notes: Same routine postoperative medications and contact lens as the intervention eye.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Bagheiat-allah 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data related to the results of the study will be shared for researchers to conduct future research

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers working in scientific and academic centers

Under which criteria data/document could be used

It will be possible to access the data by specifying the source of information and preserving the intellectual rights of patients and study researchers

From where data/document is obtainable

Ophthalmology Department of Baqiyatullah Hospital

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

After sending an email from the researcher to correspond of the study, the goals of the researcher will be checked for access to the data, and if approved, the information will be accessible in the Department of Ophthalmology of Baqiyatullah.

Comments