Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation efficacy of umbilical cord serum eye drops on corneal epithelium repair after trans-PRK refractive surgery in Baqiyatullah Hospital

Protocol summary

Study aim

Determination of the effect of fetal umbilical cord serum drops on the recovery time of damaged corneal epithelium after Trans-PRK surgery

Design

In this study, 30 patients who meet the criteria for PRK surgery will be selected. Each patient will have two eyes, one of which will receive umbilical cord serum drops, and the other will receive sterile distilled water drops. The selection of the eye will be done randomly, and the drops will be coded and identical to ensure there is no difference between them. The patients will receive routine post-PRK treatment, and initial information will be recorded in a pre-designed questionnaire. The level of pain, epithelial defects, and conjunctival redness will be recorded on the first, second, fifth, and seventh days, and the patient's vision, corneal haziness, and dry eye tests will be assessed in the first, third, and sixth months. Additionally, a confocal paraclinical test to evaluate the corneal surface nerves will be conducted before and six months after surgery.

Settings and conduct

Ophthalmology Department of Baqiyatullah Hospital

Participants/Inclusion and exclusion criteria

• Inclusion criteria: Age over 18 years indication for prk surgery Consent to participate in the study • Exclusion criteria: Failure to return for follow-up examinations after surgery

Intervention groups

The intervention groups in this study are as follows: Intervention group: The eyes that will receive umbilical cord serum drops. Control group: The eyes that will receive sterile distilled water drops.

Main outcome variables

The primary outcome variable in this study is **the improvement in corneal epithelial defects** and **pain** on the first, second, fifth, and seventh days post-surgery. These variables are among the key factors evaluated to assess the effect of umbilical cord serum drops compared to sterile distilled water drops.

General information

Reason for update

Acronym

ups

IRCT registration information

IRCT registration number: **IRCT20250105064285N1**
Registration date: **2025-02-13, 1403/11/25**
Registration timing: **prospective**

Last update: **2025-02-13, 1403/11/25**
Update count: **0**

Registration date

2025-02-13, 1403/11/25

Registrant information

Name

Mahmood Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6667 4267

Email address

maha7092@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2025-08-22, 1404/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation efficacy of umbilical cord serum eye drops on corneal epithelium repair after trans-PRK refractive surgery in Baqiyatullah Hospital

Public title

The effect of umbilical cord eyedrop on corneal repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Indication for prk surgery Consent to participate in the study

Exclusion criteria:

Failure to return for follow-up examinations after surgery

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

both eyes

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a total of 30 patients will be evaluated (one eye in the test group and the other in the control group, totaling 60 eyes). Both eyes of the patients will receive contact lenses and routine postoperative medications after PRK surgery. However, one eye will be treated with umbilical cord serum eye drops, while the other eye will receive sterile distilled water eye drops using identical vials (one drop every four hours). The selection of the eye receiving the umbilical cord serum eye drops will be determined through random allocation using a variable block method. The unit of randomization is each individual's eye.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drops are made by the manufacturing company in a completely similar and coded way in advance so that there is no difference between the fetal cord serum drop and the placebo drop, and neither the examiner nor the patient knows in which eye the fetal cord serum drop was put and in which sterile distilled water.

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

City

Tehran

Province

Tehran

Postal code

۱۴۳۵۹۱۶۴۷۱

Approval date

2024-08-10, 1403/05/20

Ethics committee reference number

IR.BMSU.BAQ.REC.1403.094

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
Improvement in corneal epithelial defects
Timepoint
on the first, second, fifth, and seventh days post-surgery
Method of measurement
By measuring the extent and size of the defect

2

Description
Pain levels
Timepoint
on the first, second, fifth, and seventh days post-surgery
Method of measurement
Through the patient's own assessment of pain intensity based on a score of 1-10

Secondary outcomes

1

Description
corneal Haziness
Timepoint
In the first, third, sixth month
Method of measurement
Through slit lamp examination

2

Description
best corrected visual aquity
Timepoint
In the first, third, sixth month
Method of measurement
Snellen chart

3

Description
dry eye tests
Timepoint
In the first, third, sixth month
Method of measurement
TBUT, Strip Test, Tear High

4

Description
Confocal paraclinical test results
Timepoint
six months after surgery
Method of measurement
printout report

Intervention groups

1

Description
Intervention Group: Eyes Receiving Umbilical Cord Blood Serum Eye DropsIn this study, one eye of each patient is randomly assigned to the intervention group and treated with Umbilical Cord Blood Serum (UCBS) Eye Drops. This treatment accelerates corneal wound healing and reduces inflammation due to the presence of growth factors, cytokines, and nutritional proteins.Equipment and ConsumablesUmbilical Cord Blood Serum (UCBS):Derived from freshly collected umbilical cord blood samples.After screening for infectious diseases, the blood is centrifuged to separate plasma.Preparation Process:The serum is stored under sterile conditions at -80°C and brought to 4°C before use.Chemical Composition:Contains growth factors (EGF, TGF-β, PDGF, VEGF), albumin, immunoglobulins, and vitamin A.Concentration:Typically 20% (one part serum diluted in four parts sterile saline solution).Dosage and AdministrationDosage: One drop every 4 hours in the intervention eye (6 times per day).Duration of Treatment: At least 7 days (or until complete corneal epithelial healing).Administration:Patients apply the drops in a sterile manner following PRK surgery, as per the treatment protocol.Comparison with the Control GroupThe contralateral eye (control eye) of the same patient receives sterile distilled water drops in visually identical vials to maintain a placebo effect.Manufacturer and Quality ControlProduction Site: Umbilical cord blood banks or authorized biological product laboratories.Quality Control:Sterility testing, microbial contamination checks, and verification of active components before use.
Category
Treatment - Drugs

2

Description
Control group: The eyes that will receive sterile distilled water drops.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatullah hospital
Full name of responsible person
Mahmood Hassani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mahmood Hassani
Position
Resident
Latest degree
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Other areas of specialty/work
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Maha7092@gmail.com

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