Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of platelet-rich plasma-derived exosome (PRP-Exosome) on the treatment of dry eye and persistent corneal defects- Interventional - before and after

Protocol summary

Study aim
To evaluate the efficacy and safety of autologous platelet-rich plasma (PRP) derived exosome eye drops in healing persistent corneal epithelial defects.

Design
Single center, single arm, pre-post interventional clinical trial without randomization, phase 1-2 pilot study on 50 patients.

Settings and conduct
Khalili Hospital, Shiraz; evaluations including slit lamp, corneal staining, visual acuity, and symptoms are done on days 0, 7, 14, and 28; no blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 years or older; persistent corneal epithelial defect unhealed for at least 2 weeks; willingness to attend 28-day follow-ups; written consent. Exclusion criteria: Active ocular infection; pregnancy or lactation; known hypersensitivity; severe systemic illness; severe thrombocytopenia.

Intervention groups
Single arm study; 50 patients receive 20% autologous PRP-derived exosome eye drops, 1 drop every 6 hours into the affected eye for 28 days.

Main outcome variables
Rate and time to complete corneal epithelial healing; corneal fluorescein staining area; best-corrected visual acuity (BCVA); clinical symptom severity score (VAS).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240706062337N3**
Registration date: **2026-10-05, 1405/07/13**
Registration timing: **prospective**
Last update: **2026-10-05, 1405/07/13**
Update count: **0**

Registration date
2026-10-05, 1405/07/13

Registrant information
Name
Fatemeh Sanie-Jahromi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3230 2830
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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2027-03-06, 1405/12/15

Expected recruitment end date
2028-03-05, 1406/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of platelet-rich plasma-derived exosome (PRP-Exosome) on the treatment of dry eye and persistent corneal defects- Interventional - before and after

Public title
Effect of Platelet-Rich Plasma-Derived Exosome Eye Drops in the Treatment of Dry Eye and Persistent Corneal

Defects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older. Clinical diagnosis of persistent corneal epithelial defect (lack of significant epithelial healing for 2 weeks or more despite standard supportive treatments) and/or dry eye-related epithelial lesions confirmed by an ophthalmologist. Ability and willingness to comply with all study follow-up visits on days 0, 7, 14, and 28. Provision of written informed consent after receiving comprehensive information regarding the study objectives, procedures, potential benefits, and risks.

Exclusion criteria:

Active ocular infection (corneal or conjunctival infection with purulent discharge) requiring immediate systemic or intensive topical antimicrobial therapy. Known history of hypersensitivity or anaphylactic reaction to blood products or preservatives used in the artificial tears. Pregnancy or breastfeeding. Concurrent use of topical or systemic medications that substantially interfere with corneal epithelial wound healing and cannot be safely discontinued (e.g., high-dose systemic corticosteroids or potent immunosuppressive agents). Severe uncontrolled systemic diseases (e.g., uncontrolled diabetes mellitus or end-stage renal/hepatic failure) that may compromise patient safety or treatment response. Baseline hematological abnormalities or markedly low platelet counts that preclude the preparation of adequate-quality autologous platelet-rich plasma (PRP). Concurrent participation in any other clinical trial that could interfere with the study interventions or outcomes.

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

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 Shiraz University of Medical Sciences

Street address

Zand Boulevard, Poostchi Street, Poostchi Ophthalmology Research Center

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Fars

Postal code

7134997446

Approval date

2026-07-29, 1405/05/07

Ethics committee reference number

IR.SUMS.REC.1405.317

Health conditions studied

1

Description of health condition studied

Dry eye disease

ICD-10 code

H04.129

ICD-10 code description

Dry eye syndrome of unspecified lacrimal gland

2

Description of health condition studied

Corneal epithelial defect

ICD-10 code

H59

ICD-10 code description

Intraoperative and postprocedural complications and disorders of eye and adnexa, not elsewhere classified

Primary outcomes

1

Description

Complete healing of the persistent corneal epithelial defect, defined as total re-epithelialization with negative corneal fluorescein staining

Timepoint

Before intervention (day 0) and days 7, 14, and 28 after intervention

Method of measurement

Slit lamp biomicroscopy examination combined with cobalt blue light digital photography following one percent sodium fluorescein eye drop instillation, and calculation of the defect area in square millimeters using digital image analysis software

2

Description

Improvement in dry eye disease severity based on tear

break-up time (TBUT) and Ocular Surface Disease Index (OSDI) score

Timepoint

Before intervention (day 0) and days 7, 14, and 28 after intervention

Method of measurement

Measurement of tear break up time in seconds using slit lamp biomicroscopy with cobalt blue illumination following instillation of sodium fluorescein solution

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Autologous platelet-rich plasma (PRP) derived exosome eye drops. Peripheral blood is obtained from the patient, and exosomes are extracted via centrifugation and platelet lysis protocols, followed by 0.22 micrometer sterile filtration. The exosomes are diluted to a 20% volume per volume concentration in an artificial tears. Patients administer 1 drop into the affected eye four times daily (every 6 hours) for 28 consecutive days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poostchi Ophthalmology Research Center

Full name of responsible person

Fatemeh Sanie-Jahromi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

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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

Fatemeh Sanie-Jahromi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular Cell Biology

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Person responsible for updating data

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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