

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation of the therapeutic effect of cellular fibrin membrane with autologous oral mucosal epithelial cells in the repair of chemical burns on the surface of the human eye - Phase 1 and 2 clinical trial

Protocol summary

Study aim

Investigation therapeutic effect of cellular fibrin membrane with autologous cells of the oral mucosa in the repair of chemical burns on the surface of the human eye - Phase 1 and 2 clinical trial

Design

Clinical trial without control group, community based, not blinded, Non-randomised controlled study

Settings and conduct

This study is related to ophthalmology field and will be done in Shafa hospital and Cell Therapy and Regenerative medicine Comprehensive Center of Kerman University of Medical Science. After case selection by physician, sample of patient's oral mucosa is prepared. After the preparation of cellular fibrin membrane with epithelial cells, the membrane is transplanted to patient's eye by physician. The patients will be follow up 7 and 28 days after transplantation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged between 18-40 years
Patients with severe corneal epithelium defect
Patients with favorable prognostic factors
Patients with normal intraocular pressure
Patients with normal light perception that shows the health of nerve of eye
Patients with no retina disease
Patient with no severe dry eye
Exclusion Criteria: Patients with severe systemic disorders
Patients with mental disorders
Pregnant women

Intervention groups

Cellular fibrin membrane with epithelial oral mucosa cells is prepared and then transplanted to patient's eye. Patients will be evaluated 7 and 28 days after transplantation.

Main outcome variables

Increase in transparency of the cornea, Increase corneal smooth surface, no evidence of vascularization in cornea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140911019125N9**

Registration date: **2020-10-11, 1399/07/20**

Registration timing: **prospective**

Last update: **2020-10-11, 1399/07/20**

Update count: **0**

Registration date

2020-10-11, 1399/07/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32 24618

Email address

afarsinejad@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of cellular fibrin membrane with autologous oral mucosal epithelial cells in the repair of chemical burns on the surface of the human eye - Phase 1 and 2 clinical trial

Public title

Treatment of ocular chemical burns with cellular fibrin membrane

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged between 18-40 years Patients with severe corneal epithelium defect Patients with favorable prognostic factors Patients with normal intraocular pressure Patients with normal light perception that shows the health of nerve of eye Patients with no retina disease Patient with no severe dry eye

Exclusion criteria:

Patients with severe systemic disorders Patients with mental disorders Pregnant women

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **15**

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 Kerman University Of Medical Science

Street address

Haft Bagh Blvd, Kerman University Of Medical Science

City

Kerman

Province

Kerman

Postal code

7616911333

Approval date

2020-10-05, 1399/07/14

Ethics committee reference number

IR.KMU.REC.1399.411

Health conditions studied

1

Description of health condition studied

Treatment of ocular chemical burns

ICD-10 code

S05.9

ICD-10 code description

Unspecified injury of eye and orbit

Primary outcomes

1

Description

Transparency of the cornea

Timepoint

Before intervention and 7 and 28 days after intervention

Method of measurement

Microscopic measurement

2

Description

Corneal smooth surface

Timepoint

Before intervention and 7 and 28 days after intervention

Method of measurement

Microscopic measurement

3

Description

Vascularization in cornea

Timepoint

Before intervention and 7 and 28 days after intervention

Method of measurement

Microscopic measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, after sampling from patients oral mucosa epithelial cells are extracted, fibrin membrane is prepared and coated with cells and then transplanted on eye surface of patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman, Shafa hospital

Full name of responsible person

Majid Shams

Street address

Kowsar Blvd, Shafa Hospital

City

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Province

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7618751151

Phone

+98 34 3211 5780

Email

shamsoph@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Alireza Farsinejad

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In our study none of the personal data of patients will be shared. Only data that are related to outcomes of intervention will be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

The data will be available for people working in academic institutions and clinicians.

Under which criteria data/document could be used

Applicants are only allowed to use received data in clinical and they are not allowed to publish them.

From where data/document is obtainable

1- Phone: 034-31325374 2- e-mail:

afarsinejad@kmu.ac.ir 3- Fax: 034-31325375 4- address:

Haft bagh Blvd, Kerman university of medical science Dr.

Alireza Farsinejad

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

Applicant can receive information after contact and send e-mail up to 10 days.

Comments