Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study the therapeutic effect of cellular fibrin membrane with autologous oral mucosa epithelial cells in treatment of ocular chemical burns in human

Protocol summary

Study aim

Investigation the therapeutic effect of cellular fibrin membrane with autologous oral mucosa epithelial cells in restoration of human chemical eye burns

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: **IRCT20140911019125N3**
Registration date: **2019-02-28, 1397/12/09**
Registration timing: **prospective**

Last update: **2019-02-28, 1397/12/09**
Update count: **0**

Registration date

2019-02-28, 1397/12/09

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

2019-04-21, 1398/02/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study the therapeutic effect of cellular fibrin membrane with autologous oral mucosa epithelial cells in treatment of ocular chemical burns in human

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
2
Groups that have been masked
No information
Sample size
Target sample size: **6**
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
2019-02-25, 1397/12/06
Ethics committee reference number
IR.KMU.REC.1397.498

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
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Postal code
7618751151
Phone
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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?
No

Title of funding source
Kerman university of medical science

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
Assistant 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 non 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 published 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