

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The Role of Amniotic Membrane Transplantation in Ocular Chemical Burns

Protocol summary

Summary

The study will be conducted on 90 patients with grade II-IV acute ocular chemical burns (Roper - Hall classification) in the first 2 weeks of injury to evaluate the role of amniotic membrane transplantation in ocular chemical burns. After topical anesthesia, all patients initially will receive first aid therapy; which included irrigation with normal saline to normalize ocular surface PH and removal of early particulate maeuil and debris. After complete examination and obtaining informed consent, the patients will be randomized using a treatment assignment list to either amniotic membrane transplantation with conventional medical therapy (group A) or medical treatment only (group B). In the patients with bilateral injuries the eyes will be randomized separately. Amniotic membrane transplantation will be performed within 24h of presentation. The patients will be examined at days 1, 3, 7, 10, 14, 21, 28 and then biweekly until 3 months and monthly until (1 year in every visit), visual acuity will be checked (by sneillen charts).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904071180N16**
Registration date: **2010-06-28, 1389/04/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-28, 1389/04/07

Registrant information

Name

pooya rostami

Name of organization / entity

Ophthalmic Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 5952

Email address

labbafi@hotmail.com

Recruitment status

Recruitment complete

Funding source

Ophthalmic Research Center

Expected recruitment start date

2006-07-12, 1385/04/21

Expected recruitment end date

2006-11-12, 1385/08/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Role of Amniotic Membrane Transplantation in Ocular Chemical Burns

Public title

The Role of Amniotic Membrane Transplantation in Ocular Chemical Burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with chemical eye burn grade 2-4, Burning has been occurred during 2 weeks ago.
Exclusion Criteria: Grade I burnings, Follow up of the patients has been disconnected in 6 month.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked
No information

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov

Secondary trial Id
NCT00370812

Registration date
2008-09-23, 1387/07/02

Ethics committees

1

Ethics committee

Name of ethics committee
Ophthalmic Research Center

Street address
No 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

City
Tehran

Postal code
166666

Approval date
2006-07-26, 1385/05/04

Ethics committee reference number
5220، ت ج

Health conditions studied

1

Description of health condition studied
Eye burn

ICD-10 code
T26

ICD-10 code description
Burn and corrosion confined to eye and adnexa

Primary outcomes

1

Description
Visual acuity

Timepoint
Days 1, 3, 7, 10, 14, 21, 28 and then every 2weeks until 3 months and monthly until 1 year

Method of measurement
snellen chart

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: amniotic membrane transplantation with conventional medical therapy

Category
Other

2

Description
Control: Medical treatment alone

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Labbafinejad Hospital

Full name of responsible person
Alireza Baradaran Raffiee, MD

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ophthalmic Research Center

Full name of responsible person
Ali-asghar Aghdai

Street address
No 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

City
Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ophthalmic Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ophthalmic Research Center

Full name of responsible person

Dr Alireza Baradaran Rafee

Position

Ophthalmologist

Other areas of specialty/work

Street address

No 23, Pasdaran Ave, 9 th Boostan, Ophthalmic Research Center

City

Tehran

Postal code

166666

Phone

+98 21 2259 2200

Fax

Email

labbafi@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Baradaran Rafiee, MD

Position

Ophthalmologist

Other areas of specialty/work

Street address

N0 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

City

Tehran

Postal code

1666663111

Phone

+98 21 2276 6106

Fax

Email

labbafi@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ophthalmic Research Center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Pooya Rostami

Position

General physician

Other areas of specialty/work

Street address

No 23, Pasdaran Ave, 9th Boostan, Ophthalmic Research Center

City

Tehran

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty