

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of topical erythropoietin on healing of chemical burn grade 3 and 4 clinical trial study

Protocol summary

Study aim

This single-blinded, stratified, randomized clinical trial was designed to evaluate the effect of topical erythropoietin on the healing of chemical burn grades 3 and 4.

Design

A randomized, single-blinded, parallel trial

Settings and conduct

All procedures are performed by a unique glaucoma surgeon (F. Jafari) in labbafinejad hospital. data analyzer is blinded in this study.

Participants/Inclusion and exclusion criteria

Patients who have suffered grade 3 and 4 corneal damage (according to the Roper-Hall classification) due to chemical burns and have presented to the labbafinejad hospital in the acute stage. Patients with a history of diabetic retinopathy, neovascular glaucoma, and eye surface tumors will be excluded from the study.

Intervention groups

Intervention group: Patients with grade 3 and 4 corneal damage according to the Roper-Hall classification due to chemical burns, in addition to standard medications, also use erythropoietin eye drops (3000 units/cc every 6 hours). Control group: Patients with grade 3 and 4 corneal damage according to the Roper-Hall classification due to chemical burns, who receive standard treatment.

Main outcome variables

Avascular lesions, epithelium defects, corneal transparency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230510058143N1**

Registration date: **2023-05-16, 1402/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-16, 1402/02/26**

Update count: **0**

Registration date

2023-05-16, 1402/02/26

Registrant information

Name

Sepehr Feizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2259 1616

Email address

sepehrfeizi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-03, 1402/02/13

Expected recruitment end date

2023-06-03, 1402/03/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical erythropoietin on healing of chemical burn grade 3 and 4 clinical trial study

Public title

Evaluation of the effect of topical erythropoietin on healing of chemical burn grade 3 and 4 clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have suffered grade 3 and 4 corneal damage (according to the Roper-Hall classification) due to chemical burns and have presented to the labbafinezhad hospital in the acute stage

Exclusion criteria:

History of diabetic retinopathy
Neovascular glaucoma
Eye surface tumors

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization will be used. Participants are divided into two parallel groups of intervention (patients in the intervention group, receiving erythropoietin eye drops) and the control group (the group that receives routine treatment) by using (block size = 4) random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present clinical trial the surgeon and patients will be aware of the classification groups (Intervention and control) and only the biostatistician who analyzed the data are blinded to label assignment of patients to each of 2 arms of the study protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine - Shahid Beheshti University of Medical Sciences (Ethics Committee)

Street address

Volenjek

City

Tehran

Province

Tehran

Postal code

193954631

Approval date

2023-05-02, 1402/02/12

Ethics committee reference number

IR.SBMU.MSP.REC.1402.046

Health conditions studied

1

Description of health condition studied

Treatment of chemical burns of the eye surface

ICD-10 code

S05.9

ICD-10 code description

Unspecified injury of eye and orbit

Primary outcomes

1

Description

Avascular lesions

Timepoint

First day of examination, first week, first month, third and fourth

Method of measurement

by PhotoSlit and and with the help of Image J software by an operator

2

Description

Epithelial defect

Timepoint

First day of examination, first week, first month, third and fourth

Method of measurement

Fluorescein staining by the ophthalmologist

3

Description

Corneal transparency

Timepoint

First day of examination, first week, first month, third and fourth

Method of measurement

Roper-Hall classification

Secondary outcomes

1

Description

Best corrected visual acuity (BCVA)

Timepoint

First day of examination, first week, first month, third and fourth

Method of measurement

Tumbling E-chart

Intervention groups

1

Description

Intervention group: Patients with grade 3 and 4 corneal damage according to the Roper-Hall classification due to chemical burns, in addition to standard medications, also use erythropoietin eye drops (3000 units/cc every 6 hours).

Category

Treatment - Drugs

2

Description

Control group: Patients with grade 3 and 4 corneal damage according to the Roper-Hall classification due to chemical burns, who receive standard treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

labbafinejad hospital

Full name of responsible person

Fatemeh Jafari

Street address

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Fatima.jafari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sepehr Feizi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Jafari

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Jafari

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

Street address

Velenjak

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 further information

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