Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of 40% autologous serum drop with artificial tear drop in improving corneal epithelial injury after corneal collagen cross-linking surgery, epithelium-off: a double-blind randomized controlled trial).

Protocol summary

Study aim

main objective: Comparison of the effect of 40% autologous serum drop with an artificial tear drop in improving corneal epithelial injury after corneal collagen cross-linking surgery, epithelium-off

Design

Using computer software (Random Allocation Software), the study subjects are placed into two intervention groups through blocks of four and six with an allocation ratio of 1:1 in two groups. The random allocation sequence will be generated by a person not involved in the research. The drops will be numbered according to the generated sequence from 1 to 34.

Settings and conduct

In this double-blind randomized controlled trial, patients with keratoconus will be included in the study and will be randomly divided into two intervention groups (40% autologous serum drop) and control group (artificial tear drop). First, one eye of the patients will be operated. Then the second eye will also operated and then the patients will be followed up for 2 weeks. Autologous serum drop every two hours along with a topical antibiotic every 6 hours will be used by the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with bilateral keratoconus ready for surgery, none of whose eyes have been cross-linked before. 2- Consent to participate in the study Exclusion criteria: Patients with corneal thickness less than 400 microns, history of ocular herpes, recent history of any type of eye infection, presence of corneal scarring or opacity, neurotrophic keratopathy, positive history of autoimmune diseases and pregnancy

Intervention groups

intervention group (40% autologous serum drop) and control group (artificial tear drop).

Main outcome variables

pain intensity; Epithelium closure time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161218031450N6**
Registration date: **2023-10-29, 1402/08/07**
Registration timing: **retrospective**

Last update: **2023-10-29, 1402/08/07**
Update count: **0**

Registration date

2023-10-29, 1402/08/07

Registrant information

Name

Ali Mostafaie

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3655 1332

Email address

mostafaeia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-09, 1402/06/18

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

2023-09-06, 1402/06/15

Actual recruitment end date

2023-10-23, 1402/08/01

Trial completion date

2023-10-23, 1402/08/01

Scientific title

Comparison of the effect of 40% autologous serum drop with artificial tear drop in improving corneal epithelial injury after corneal collagen cross-linking surgery, epithelium-off: a double-blind randomized controlled trial).

Public title

Comparison of the effect of 40% autologous serum drop with artificial tear drop in improving corneal epithelial injury after corneal collagen cross-linking surgery,

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with bilateral keratoconus ready for surgery, none of whose eyes have been cross-linked before. Consent to participate in the study Patients with keratoconus in both eyes

Exclusion criteria:

Patients with a corneal thickness less than 400 microns history of ocular herpes recent history of any type of eye infection presence of corneal scarring or opacity neurotrophic keratopathy positive history of autoimmune diseases Pregnancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Using computer software (Random Allocation Software), the study subjects are placed into two intervention groups through blocks of four and six with an allocation ratio of 1:1 in two intervention groups (40% autologous serum) or control (artificial tear drops). The random allocation sequence will be generated by a person not involved in the research. The drops will be numbered according to the generated sequence from 1 to 34. The first drop will be given to the first patient who is eligible for the study and this will continue until the samples are completed. How to use eye drops will be taught

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients will be divided into two groups based on the randomization form. The patients and outcome assessor will not know how the drug was used. The data analyzer will also be unaware of how the drug is used in both groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

tabriz university of medical science

Street address

abbasi street, nikookari eye hospital

City

tabriz

Province

East Azarbaijan

Postal code

4514436452

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.TBZMED.REC.1402.436

Health conditions studied

1

Description of health condition studied

Keratoconus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

corneal epithelium closure

Timepoint

1,2,3 post op days.

Method of measurement

with slit lamp

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
nikookari eye hospital
Full name of responsible person
sajjad soltani
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abbasi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Ali Mostafaei
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
resident

Latest degree
Specialist

Other areas of specialty/work
Ophthalmology

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available