

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effectivness of autologous serum in Corneal Epithelial defect healing

Protocol summary

Summary

Effectivness of autologous serum in corneal epithelial defect healing: A randomized control trial Inclusion criteria: minimum age 18; stable refraction for at least 1 year; normal corneal topography. Exclusion criteria: unstable refraction; dry eye; blepharitis; corneal disease; glaucoma. Forty eyes of 20 patients received autologous serum drops (study group) and conventional artificial tears (control group) randomly after PRK. Time to epithelial healing was the main outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122531450N3**

Registration date: **2017-05-26, 1396/03/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-26, 1396/03/05

Registrant information

Name

Ali Mostafaie

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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mostafaeia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectivness of autologous serum in Corneal Epithelial defect healing

Public title

Effectivness of autologous serum in corneal superficial layer healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: minimum age 18; stable refraction for at least 1 year; normal corneal topography with minimum central thickness 500; stop using daily wear lens at least 1 week before; Exclusion criteria; unstable refraction; dry eye; blepharitis; corneal disease; glaucoma; systemic disease; abnormal topography and keratoconus

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded
Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Central building of the University, Golgasht street, Azadi street, Tabriz

City

Tabriz

Postal code

51666-16471

Approval date

2016-10-10, 1395/07/19

Ethics committee reference number

IR.TBZMED.REC.1395.798

Health conditions studied

1

Description of health condition studied

Refraction

ICD-10 code

H52

ICD-10 code description

Hypermetropia,Myopia,Astigmatism

Primary outcomes

1

Description

Time to corneal epithelial healing

Timepoint

day 1,2,3, and 7

Method of measurement

slit lamp examination

Secondary outcomes

1

Description

pain

Timepoint

day1,2,3,7,month1

Method of measurement

check list

2

Description

corneal opacity

Timepoint

day1,2,3,7 month1,6

Method of measurement

slit lamp

3

Description

visual acuity

Timepoint

month1,6

Method of measurement

snellen chart

Intervention groups

1

Description

Autologous serum eye drop 20% every 6hours(4times a day)until corneal epithelial defect healing.(intervention)

Category

Treatment - Drugs

2

Description

Conventional artificial tears every 6 hours(4times a day)until corneal epithelial defect healing.(control)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikookari Hospital

Full name of responsible person

Dr Siamak Nejatbakhsh/Resident of ophthalmology

Street address

Nikookari Hospital, Abbassi Street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nikookari Ophthalmology Research Center,Tabriz
University of Medical Sciences

Full name of responsible person

Siamak Nejatbakhsh

Street addressCentral building of the university, Golgasht street,
Azadi street, Tabriz**City**

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceNikookari Ophthalmology Research Center, Tabriz
University of Medical Sciences**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**

Tabriz University of Medical Sciences

Full name of responsible person

Siamak Nejatbakhsh

Position

Ophthalmology Assistant

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ali Mostafaie

PositionSurgeon and Ophthalmologist, Fellowship anterior
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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*