Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectivness of autologous serum in Corneal Epitelial defect healing

Protocol summary

Summary
Effectivness of autologous serum in corneal epitelial defect healing: A randomized control trial Inclusion criteria: minimum age 18; stable refraction for at least 1 year; normal corneal topography. Exclosion criteria: unstable refraction; dry eye; belepharitis; corneal diesese; 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)
Phone
+98 41 3655 1332
Email address
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 Epitelial 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 centeral thickness 500; stop useing daily wear lens at least 1 weak before; Exclosion criteria; unstable refraction;dry eye; belepharitis; corneal diesese; glaucoma; systemic diesese; abnormal topography and kratoconus
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 epitelial 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
snelen 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 address
Central 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 source
Nikookari 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
Ophthalmplogy Assistant
Other areas of specialty/work
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
51666-16471
Phone
+98 41 3335 5921
Fax
+98 41 3335 9680
Email
info@elibrary.tbzmed.ac.ir; dln@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Ali Mostafaie
Position
Surgeon and Ophthalmologist, Fellowship anterior segment
Other areas of specialty/work
Street address
Central beuoilding of the university, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
51666-16471
Phone
+98 41 3335 5921
Fax
+98 41 3335 9680
Email
info@elibrary.tbzmed.ac.ir; dln@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Siamak Nejatnakhsh
Position
Ophthalmology Assitant
Other areas of specialty/work
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
Tabriz
Postal code
51666-16471
Phone
+98 41 3335 5921
Fax
+98 41 3335 9680
Email
info@elibrary.tbzmed.ac.ir; dln@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

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