

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of effects & complications of CCL surgery with 2 methods of Epithelium removal & Trans Epithelial with using DAYA epithelium disruptor: A Randomized-Controlled Clinical Trial

Protocol summary

Summary

This study is designed to evaluate and compare safety & efficacy of Collagen Cross-Linking with 2 methods of Epithelium removal (Conventional Method) & Trans Epithelial with using DAYA epithelium disruptor. 50 patients of binocular Keratoconus of two centers of Poostchi & Motahari with age ≤ 25 years and/or with progression at age > 25 years were included. Variables like Uncorrected and corrected visual acuity, Keratoconus indices according to Pentacam® imaging and endothelial cell count are measured. With stratified randomization, first the eyes and then in each group, one of the methods is chosen, undergo the procedure and the next eye undergone the other method, 2 weeks later. Inclusion Criteria: Those with Rabinowitz criteria of keratoconus of both eyes; age ≤ 25 years; increase of at least 1 diopter of Kmax within last 12 months for age > 25 years. Exclusion criteria: Corneal Thickness of less than 400 microns; Kmax more than 61D; previous herpetic infection; Concurrent keratitis; Severe corneal opacity; history of poor epithelial healing; Autoimmune diseases; Severe ocular surface diseases. Both the patient and the analyzer are blind to the type of the method used for each eye. After one year of follow up, abovementioned variables are measured again and undergone analysis.

General information

Acronym

CCLRD

IRCT registration information

IRCT registration number: **IRCT2016112231028N1**

Registration date: **2017-03-29, 1396/01/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-29, 1396/01/09

Registrant information

Name

Seyed Mohammad Salar Zaheryani

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 1510

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smszaheryany@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-02-15, 1395/11/27

Expected recruitment end date

2018-03-15, 1396/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects & complications of CCL surgery with 2 methods of Epithelium removal & Trans Epithelial with using DAYA epithelium disruptor: A Randomized-Controlled Clinical Trial

Public title

Comparison of effects & complications of Collagen Cross-

Linking surgery with 2 methods of Epithelium removal & Trans Epithelial with using DAYA epithelium disruptor: A Randomized- Controlled Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Those with Rabinowitz criteria of keratoconus of both eyes; age \leq 25 years; increase of at least 1 diopter of Kmax within last 12 months for age $>$ 25 years. Exclusion criteria: Corneal Thickness of less than 400 microns; Kmax more than 61D; previous herpetic infection; Concurrent keratitis; Severe corneal opacity; history of poor epithelial healing; Autoimmune diseases; Severe ocular surface diseases.

Age

From **18 years** old to **46 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Committee of ethics in research of school of medicine

Street address

Shiraz University Of Medical Sciences

City

Shiraz

Postal code

Approval date

2017-01-23, 1395/11/04

Ethics committee reference number

IR.SUMS.MED.REC.1395.72

Health conditions studied

1

Description of health condition studied

keratoconus

ICD-10 code

H18.6

ICD-10 code description

No description was found

Primary outcomes

1

Description

K max

Timepoint

pre and post op

Method of measurement

Using pentacam imaging

2

Description

Time required for reepithelialization

Timepoint

post op, at days 1-3-5 & 7

Method of measurement

Slit lamp exam

3

Description

Uncorrected Visual acuity

Timepoint

pre and post op

Method of measurement

Physical exam

4

Description

Corrected Visual Acuity

Timepoint

pre and post op

Method of measurement

Physical exam

5

Description

Endothelial Cell Count

Timepoint

pre and post op

Method of measurement

Specular Microscopy

Secondary outcomes

1

Description

Sterile corneal infiltration

Timepoint

post op
Method of measurement
physical exam

2

Description
keratitis
Timepoint
post op
Method of measurement
physical exam

3

Description
corneal scar
Timepoint
post op
Method of measurement
physical exam

Intervention groups

1

Description
Control Group: Corneal epithelium is removed completely by FUKASAKU Hockey Knife and then standard solution of riboflavin 0.1% with intervals of 3 minutes distilled into eye for 30 min. Then with irradiation of UV-A with wavelength of 365-370 nm & power of 9mW/cm² and short distance from the eye (about 5 cm) for 10 min, distillation continued. Finally, irrigation with 30 ml of BSS and applying therapeutic lens over the eye, the procedure is completed.

Category
Treatment - Surgery

2

Description
Intervention Group: Corneal epithelium is disrupted incompletely by DAYA epithelial disruptor and then standard solution of riboflavin 0.1% with intervals of 3 minutes distilled into eye for 30 min. Then with irradiation of UV-A with wavelength of 365-370 nm & power of 9mW/cm² and short distance from the eye (about 5 cm) for 10 min, distillation continued. Finally, irrigation with 30 ml of BSS and applying therapeutic lens over the eye, the procedure is completed.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Poostchi Ophthalmology Center
Full name of responsible person

Dr M. Hossein Norozzadeh
Street address
Zand Street
City
Shiraz

2

Recruitment center
Name of recruitment center
Shahid Motahhari Poly Clinic
Full name of responsible person
Dr Hossein Jamali
Street address
Namazi Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Shiraz University of Medical Sciences
Full name of responsible person
Seyed Masoom Masoompour
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research of Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
S.M. Salar Zaheryani
Position
Resident of Ophthalmology

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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*