Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Oct 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
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Iran (Islamic Republic of)
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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 ≤ 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

Other areas of specialty/work
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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