

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the association between clinical and ocular characteristics with the outcomes of corneal collagen cross-linking (CXL) in patients with keratoconus (KC)

Protocol summary

Study aim

Investigating the association between clinical and ocular characteristics with the outcomes of corneal collagen cross-linking (CXL) in patients with keratoconus (KC)

Design

Clinical trial without control group and only

Settings and conduct

This study was a prospective cohort study that enrolls all possible cases (85 eyes) of surgical naive KC who were candidate for CXL, were visited in Feiz Eye Hospital affiliated to Isfahan University of medical sciences, Isfahan, Iran. At the surgical day, demographic information including sex, age and smoking, and familial history of kc, clinical diagnosis including visual acuity, intraocular pressure, biomicroscope slit lamp, ophthalmoscopy indiameter, pentacon imaging and laboratory tests including surface markers for tear biomarkers were collected. Patients were visited from one day and three days after surgery for possible complications including corneal opacity, refractive back disorder. The next day, three days, 90 days and one year after the intervention, clinical and laboratory cases and possible complications were evaluated and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: keratoconus patients who are newly candidates for corneal collagen cross-linking. Patient satisfaction. Non-Inclusion criteria: other corneal diseases. pregnancy, and breastfeeding period. Patients who have any of the following concomitant ocular diseases: diabetic macular edema, age-related macular degeneration.

Intervention groups

A total of 85 patients with keratoconus were evaluated for visual acuity, intraocular pressure, and tear biomarkers prior to surgery for collagen cornea linkages. Three days later, 90 days later and one year later, these cases were measured and recorded.

Main outcome variables

Visual acuity, intraocular pressure, surface of tear biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131229015975N4**

Registration date: **2019-05-02, 1398/02/12**

Registration timing: **retrospective**

Last update: **2019-05-02, 1398/02/12**

Update count: **0**

Registration date

2019-05-02, 1398/02/12

Registrant information

Name

Mohsen Pourazizi

Name of organization / entity

Semnan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2017-08-23, 1396/06/01
Actual recruitment end date
 2019-01-20, 1397/10/30
Trial completion date
 2019-01-20, 1397/10/30

Scientific title
 Investigating the association between clinical and ocular characteristics with the outcomes of corneal collagen cross-linking (CXL) in patients with keratoconus (KC)

Public title
 Investigating the association between clinical and ocular characteristics with the outcomes of corneal collagen cross-linking (CXL)

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient satisfaction keratoconus patients who are newly candidates for corneal collagen cross-linking
Exclusion criteria:
 Patients who have any of the following concomitant ocular diseases: diabetic macular edema, age-related macular degeneration. other corneal diseases pregnancy, and breastfeeding period

Age
 No age limit

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **85**
 Actual sample size reached: **85**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Isfahan University of Medical Sciences
Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.
City
 Isfahan
Province
 Isfahan
Postal code
 81746-73461
Approval date
 2017-08-09, 1396/05/18
Ethics committee reference number
 IR.MUI.RES.1396.3.545

Health conditions studied

1

Description of health condition studied
 Keratoconus
ICD-10 code
 H18.6
ICD-10 code description
 Keratoconus

Primary outcomes

1

Description
 Visual acuity
Timepoint
 Before surgery and six months after surgery.
Method of measurement
 Snellen chart

2

Description
 Corneal power
Timepoint
 Before surgery and six months after surgery.
Method of measurement
 Pentacam imaging

Secondary outcomes

1

Description
 Levels of tear biomarkers
Timepoint
 Before surgery and six months after surgery.
Method of measurement
 The lab using ELISA TEAR IL6 and Tear TNF- α tests

Intervention groups

1

Description
 Intervention group: 85 patients with keratoconus,

underwent corneal cross-collagen surgery to improve the patient's vision and prevent disease progression. Visual acuity, intraocular pressure, and tear biomarkers were measured by pentacet imaging and ELISA TEAR IL6 and Tear TNF- α tests. The time intervals before surgery and six months later, were evaluated.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital in Isfahan

Full name of responsible person

Alireza Peyman

Street address

Quds Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Faraj Zadegan

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar Jerib Avenue.

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dean@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohsen Pourazizi

Position

M.D.

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Alireza Peyman

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information is available after being unidentifiable and two years after the publication of the article.

When the data will become available and for how long

two years after the publication of the article.

To whom data/document is available

Assistants and Ophthalmologists

Under which criteria data/document could be used

To compare the available information with information that is available at another time by another researcher.

From where data/document is obtainable

Send an application to drpeyman@hotmail.com and get permission from the research vice president of Isfahan University of Medical Sciences.

What processes are involved for a request to access data/document

Send an application to drpeyman@hotmail.com and get permission from the research vice president of Isfahan University of Medical Sciences.

Comments