Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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

Isfehan

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Street address

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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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Full name of responsible person

Dr. Alireza Peyman

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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