

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between accelerated and conventional methods of Cornea collagen crosslinking in prognosis of keratoconus patients, referred to Feiz hospital in 2013

Protocol summary

Summary

Keratoconus is a progressive disorder that usually presents in patients during their twenties. The cornea gets thin and changes shape. Today a new method is suggested in treatment of keratoconus, named cross-linking; this method, which can be performed in a usual 30-minute surgery or a newer 5-minute surgery, is fast and relatively pain free and has led to remarkably good results. Up to this date few studies have been done on the usual and accelerated cross-linking methods, comparison between them and their prognosis. The aim of this study is to compare the prognosis of patients with keratoconus between usual and accelerated methods of cross-linking procedure. The study is conducted as randomized clinical trial, including two groups of intervention. Forty patients with keratoconus, matching the inclusion criteria, will be enrolled and randomly divided into two groups. Baseline values of variables, including visual acuity, refractory errors, keratometric and topographic indexes will be collected from both groups. One group will undergo a routine 30-minute procedure while the other is treated with a faster, 5-minute, procedure according to the established protocols of cross linking surgery. Same variables will be measured after 6 months and the data will be measured against its base line value and the data acquired from the other group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040912960N1**
Registration date: **2013-05-11, 1392/02/21**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-11, 1392/02/21

Registrant information

Name

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Name of organization / entity

Isfahan University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of medical sciences department of research and technology

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between accelerated and conventional methods of Cornea collagen crosslinking in prognosis of keratoconus patients, referred to Feiz hospital in 2013

Public title

Comparison between accelerated and conventional

methods of Cornea collagen crosslinking in keratoconus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: documented keratoconus patients who had refractive error higher than 2 diopters and were willing to participate in the study. Exclusion criteria: patients with poor compliance, who do not follow the post-operation orders precisely and confound the results, such as avoiding to take their medicine or not taking them correctly; patients who are affected with endophthalmitis or any other ophthalmic diseases after surgery; patients with systemic diseases such as collagen vascular disease.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jarib street, Azadi square

City

Isfahan

Postal code

Approval date

2011-11-17, 1390/08/26

Ethics committee reference number

391326

Health conditions studied

1

Description of health condition studied

keratoconus

ICD-10 code

H18.6

ICD-10 code description

conical cornea

Primary outcomes

1

Description

Visual acuity

Timepoint

Before intervention, 6 months after intervention

Method of measurement

Snellen chart

2

Description

Keratometric evaluation

Timepoint

Before intervention, 6 months after intervention

Method of measurement

Pentacam anterior SimK

3

Description

Topographic evaluation

Timepoint

Before intervention, 6 months after intervention

Method of measurement

Pentacam Scheimpflug imagery

4

Description

Refractory error

Timepoint

Before intervention, 6 months after intervention

Method of measurement

Auto refractive

Secondary outcomes

empty

Intervention groups

1

Description

Usual 30-minute cross link surgery of keratoconus , using riboflavin and florescent light to stabilize corneal collagen and prevent progressive destruction of cornea

Category

Treatment - Surgery

2

Description

Accelerated 5-minute cross link surgery of keratoconus , using riboflavin and uniform florescent light to stabilize corneal collagen and prevent progressive destruction of cornea

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Alireza Peiman M.D.

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences, Research and technology department

Full name of responsible person

Peiman Adibi M. D.

Street address

Isfahan University of Medical Sciences, Hezar jarib street, Azadi square

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences, Research and technology department

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

Isfahan University of Medical Sciences

Full name of responsible person

Alireza Peiman M.D.

Position

Assistant Professor, Department of Ophthalmology, Isfahan University of Medical Sciences

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