Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

comparison of 30 minutes and 5 minutes collagen cross-linking in patients with keratoconus

Protocol summary

Summary

Objective of the study is comparison of 30 min- and 5 min- ultraviolet radiation in cross-linking treatment among keratoconic cornea. 30 patients with advanced progressive bilateral keratoconus were enrolled after signing written consent form. The eyes were randomly assigned to conventional (30 min) and new method (5 min) of radiation on the basis of balance blocked randomization. All routine clinical examinations and paraclinical tests were performed for the patients before the operation. Then they were examined 1, 3 and 6 months after the operation, and following tests were conducted for them: visual acuity, refraction, corneal biomechanical assessment, endothelial cell count, and corneal topography. Patients do not pay for these tests. Finally, after comparing the two procedures, the preferred method is introduced.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207244333N1**
Registration date: **2012-08-30, 1391/06/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-30, 1391/06/09

Registrant information

Name
Soheila Asgari
Name of organization / entity
Noor eye hospital
Country
Iran (Islamic Republic of)
Phone
+98 21 8865 1515
Email address
sasgari@noorvision.com

Recruitment status

Recruitment complete

Funding source

Research funding in Noor eye hospital

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-02-18, 1391/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of 30 minutes and 5 minutes collagen cross-linking in patients with keratoconus

Public title

New treatment of keratoconus with UV

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: keratometry less than 60 diopter; central corneal thickness of 400 microns or more; keratoconus progression in the past 12 months documented as at least one D increase in maximum keratometry, or manifest cylinder; Bilateral surgery
Exclusion criteria: diabetes and other systematic disease; use of corticosteroid and immunosupressive drugs in the past 6 months

Age

From **15 years** old to **35 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Noor eye hospital
Street address
#96 Esfandiar Blvd., Vali’asr Ave.
City
Tehran
Postal code
1968653111
Approval date
2012-07-26, 1391/05/05
Ethics committee reference number
757/ρ

Health conditions studied

1

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

Primary outcomes

1

Description
corneal biomechanical assay
Timepoint
pre op, 1m, 3m and 6m after surgery
Method of measurement
Cornea status is evaluated by Ocular Response Analyzer (ORA), confoscan, and endothelial cell count (ECC)

Secondary outcomes

1

Description
Refraction
Timepoint
pre op, 1m, 3m and 6m after surgery
Method of measurement
autorefractometer

2

Description
Keratometry
Timepoint
pre op, 1m, 3m and 6m after surgery
Method of measurement
Pentacam

3

Description
Visual acuity
Timepoint
pre op, 1m, 3m and 6m after surgery
Method of measurement
Snellen chart

Intervention groups

1

Description
Intervention name: 5 min-UV radiation in corneal cross-linking Intervention description: After local anesthesia with Proparacaine hydrochloride 0.5% eye drop, 3 or 4 vertical strips about 2 mm wide remove from the central 8-9 mm corneal epithelium. Then, riboflavin 0.1% drop in dextra 20% is instilled onto the cornea every 3 minutes for half an hour (a total of 10 times). At the end of this stage, the patient is examined by the slit lamp to ensure the presence of riboflavin and yellow tindall in the anterior chamber. Then, ultraviolet irradiation at a wavelength of 370 nanometer, a width of 9 mm, power 3mW/cm2 and a distance of 5cm is started. In interventional group, Ultraviolet irradiation is continued for 5 minutes. At the end of irradiation, the corneal surface is rinsed with sterile balanced saline solution, a soft bandage contact lens was placed. Chloramphenicol and betamethasone eye drop will be prescribed at discharge.
Category
Treatment - Surgery

2

Description
The control intervention: 30 min-UV radiation in corneal cross-linking (routin treatment) Control intervention description: After local anesthesia with Proparacaine hydrochloride 0.5% eye drop, 3 or 4 vertical strips about

2 mm wide remove from the central 8-9 mm corneal epithelium. Then, riboflavin 0.1% drop in dextra 20% is instilled onto the cornea every 3 minutes for half an hour (a total of 10 times). At the end of this stage, the patient is examined by the slit lamp to ensure the presence of riboflavin and yellow tindall in the anterior chamber. Then, ultraviolet irradiation at a wavelength of 370 nanometer, a width of 9 mm, power 3mW/cm2 and a distance of 5cm is started. In control group, Ultraviolet irradiation is continued for 30 minutes. At the end of irradiation, the corneal surface is rinsed with sterile balanced saline solution, a soft bandage contact lens was placed. Chloramphenicol and betamethasone eye drop will be prescribed at discharge.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor eye hospital

Full name of responsible person

Dr Hassan Hashemi, fellowship in cornea and anterior segment, professor

Street address

#96 Esfandiar Blvd., Vali’asr Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Noor eye hospital

Full name of responsible person

DR Hassan Hashemi

Street address

#96 Esfandiar Blvd., Vali’asr Ave.

City

Tehran

Grant name

امور پژوهشی بیمارستان نور

Grant code / Reference number

91-0504

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

Yes

Title of funding source

Noor eye hospital

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

Noor eye hospital

Full name of responsible person

Soheila Asgari

Position

MS in Epidemiology

Other areas of specialty/work

Street address

#96 Esfandiar Blvd., Vali’asr Ave.

City

Tehran

Postal code

1968653111

Phone

+98 21 8240 1621

Fax

+98 21 8865 1514

Email

soheilaasgari@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Noor ophthalmology research center, Noor eye hospital

Full name of responsible person

Hassan Hashemi

Position

fellowship in cornea and anterior segment

Other areas of specialty/work

Street address

#96 Esfandiar Blvd., Vali’asr Ave.

City

Tehran

Postal code

1968653111

Phone

+98 21 8865 1515

Fax

+98 21 8865 1514

Email

hhashemi@noorvision.com

Web page address

Person responsible for updating data

Contact

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