Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of clinical results of two pharmaceutical products of Riboflavin in corneal collagen Cross-Linking for keratoconus

Protocol summary

Summary

This study is performed to compare the results of two formulations of Riboflavin by Sina Darou, Iran, and Uznach, Switzerland, in corneal collagen cross-linking (CXL) for keratoconus patients. Thirty eyes is compared in each group. The inclusion criterion is the clinical diagnosis of progressive keratoconus with paraclinical confirmation. Patients with other ocular diseases or a history of ocular surgery will be excluded from the study. Participants discontinue the use of the hard and soft contact lens 3 weeks and 3 days prior to the surgery, respectively. The intervention is standard collagen cross linking. After removal of the central of the cornea, Iranian (intervention group) or Switzerland (control group) Riboflavin will be prescribed. At first, the method and objectives of the study will be explained to the participants and a written informed consent was obtained from each of them for participation in the study and use of Iranian riboflavin. The patients will be examined before procedure and 1, 3, 6, and 12 months after it.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212034333N2**
Registration date: **2014-02-25, 1392/12/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-02-25, 1392/12/06

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

Noor Eye Hospital

Expected recruitment start date

2014-04-06, 1393/01/17

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical results of two pharmaceutical products of Riboflavin in corneal collagen Cross-Linking for keratoconus

Public title

Comparison of of two pharmaceutical products of Riboflavin for keratoconus

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criterion is the clinical diagnosis of progressive keratoconus with paraclinical confirmation. The criteria of progressive keratoconus is an increase of at least 1D in maximum keratometry, astigmatism, or manifest refraction, or loss of 2 best corrected visual acuity (BCVA) lines or more in the past 12 months.

Patients aged 15-35 years old with keratometry less than 55D and a central corneal thickness less than 400 µ will be selected for the study. Patients with other ocular diseases or a history of ocular surgery will be excluded from the study. Participants discontinue the use of the hard and soft contact lens 3 weeks and 3 days prior to the surgery, respectively.

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)
Not 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
Noor Ophthalmology Research Center

Street address
#96 Esfandiar Blvd., Vali’asr Ave.

City
Tehran

Postal code
1968653111

Approval date
2013-09-18, 1392/06/27

Ethics committee reference number
882/۴

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
pre operative and 1, 3, 6, and 12 months after the procedure

Method of measurement
Snellen chart

2

Description
refraction

Timepoint
pre operative and 1, 3, 6, and 12 months after the procedure

Method of measurement
retinoscope

3

Description
corneal topography

Timepoint
pre operative and 1, 3, 6, and 12 months after the procedure

Method of measurement
pentacam

4

Description
corneal rigidity

Timepoint
pre operative and 1, 3, 6, and 12 months after the procedure

Method of measurement
ORA

5

Description
Endothelial cell count

Timepoint
pre operative and 1, 3, 6, and 12 months after the procedure

Method of measurement
non-contact specular microscope

Secondary outcomes

1

Description
Corneal Haze

Timepoint
1, 3, 6, and 12 months after surgery

Method of measurement
Opthalmic examination

Intervention groups

1

Description

Interventional group: After local anaesthesia, the central 7 mm corneal epithelium will be manually removed as 3 or 4 vertical strips about 2 mm wide and 1-mm strips of epithelium will be left untouched in between. Another strip will be removed horizontally at the inferior third of the cornea. Then, riboflavin 0.1% drop in dextra 20% (SinaDarou, Iran) will be instilled onto the cornea every 3 minutes for half an hour. At the end of this stage, the patient will be examined by an ophthalmologist to ensure the presence of riboflavin in the anterior chamber. Then, ultraviolet irradiation at a wavelength of 370 nanometer, power 3mW/cm2 and a distance of 5cm will be started. For this purpose, the UVX system (IROC, Zürich, Switzerland) will be used. Ultraviolet irradiation will be continued for 30 minutes, during which, riboflavin instillation will be repeated every 3 minutes. At the end of irradiation, the corneal surface will be rinsed with sterile balanced saline solution, a soft bandage contact lens was placed, and chloramphenicol 0.5% eye drop will be instilled. Treatment will be started with chloramphenicol 0.5% eye drop four times daily, betamethasone 0.1%, and preservative free artificial tears. Patients will be examined on the next day and 3 days after surgery, and the contact lens will be removed if epithelial healing is complete. After removing the contact lens, chloramphenicol will be discontinued and betamethsaone will be continued twice daily for one week and then discontinued. If the epithelial healing will not be complete on the third day, the patient will be visited daily until complete healing.

Category

Other

2

Description

Control group: After local anesthesia, the central 7 mm corneal epithelium will be manually removed as 3 or 4 vertical strips about 2 mm wide and 1-mm strips of epithelium will be left untouched in between. Another strip will be removed horizontally at the inferior third of the cornea. Then, riboflavin (Swiss made) 0.1% drop in dextra 20% (SinaDarou, Iran) will be instilled onto the cornea every 3 minutes for half an hour. At the end of this stage, the patient will be examined by an ophthalmologist to ensure the presence of riboflavin in the anterior chamber. Then, ultraviolet irradiation at a wavelength of 370 nanometer, power 3mW/cm2 and a distance of 5cm will be started. For this purpose, the UVX system (IROC, Zürich, Switzerland) will be used. Ultraviolet irradiation will be continued for 30 minutes, during which, riboflavin instillation will be repeated every 3 minutes. At the end of irradiation, the corneal surface will be rinsed with sterile balanced saline solution, a soft bandage contact lens was placed, and chloramphenicol 0.5% eye drop will be instilled. Treatment will be started with chloramphenicol 0.5% eye drop four times daily, betamethasone 0.1%, and preservative free artificial tears. Patients will be examined on the next day and 3 days after surgery, and the contact lens will be removed if epithelial healing is complete. After removing the contact lens, chloramphenicol will be discontinued and betamethsaone will be continued twice daily for one week and then discontinued. If the epithelial healing will not be complete on the third day, the patient will be visited daily until complete healing.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Eye Hospital

Full name of responsible person

Soheila Asgari

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

Farhad Rezvan

Street address

#96 Esfandiar Blvd., Vali’asr Ave.

City

Tehran

Grant name

Grant code / Reference number

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 Ophthalmology Research Center

Full name of responsible person

Soheila Asgari

Position

Reasercher

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Noor Eye Hospital

Full name of responsible person

Soheila Asgari

Position

PhD student in Ophthalmic Research

Other areas of specialty/work

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Contact

Name of organization / entity

Noor Eye Hospital

Full name of responsible person

Soheila Asgari

Position

Researcher

Other areas of specialty/work

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Web page address

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