# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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/م

## 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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## Person responsible for updating data

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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*