

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of effect of Accelerated and Standard Corneal Cross-linking in Down Syndrome keratoconic patients: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Comparison of one-year efficacy of accelerated cross-linking (9 mW/cm<sup>2</sup>, 10 min) and standard protocol (3 mW/cm<sup>2</sup>, 30min) in Down syndrome patients with progressive keratoconus

##### Design

In this concealed parallel RCT, 30 Down patients with a definite bilateral progressive keratoconus will enroll. Based on balanced block randomization, one eye of each patient is selected for accelerated group and the fellow eye is treated by the standard protocol as the control. The surgeries are done under anesthesia. Parents complete the consent form prior to the procedure. Corvis and Pentacam tests are performed before and one-year after cross-linking.

##### Settings and conduct

This study is performed at Noor Eye Hospital, Tehran. To concealment, randomization will be done by another one not the surgeon. The patients, parents and optometrist (examiner of outcomes) will be masked to the treatment group of each eyes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: definite Down syndrome, Progressive keratoconus, age 10-30 years and minimum cooperation to imaging and examinations. Exclusion criteria: concurrent intellectual disability such as autism and klinefelter, history of ophthalmic surgery and corneal pathology such as pterygium.

##### Intervention groups

Intervention group: The one eye of bilateral case will undergo 10-min protocol of cross-linking, randomly. Control group: The fellow eye of patient will undergo 30-min method of cross-linking. All procedures will be performed under general anesthesia in operation room.

##### Main outcome variables

one-year change in corneal biomechanics; one-year change in corneal topographic indices.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100706004333N3**

Registration date: **2018-07-10, 1397/04/19**

Registration timing: **prospective**

Last update: **2018-07-10, 1397/04/19**

Update count: **0**

##### Registration date

2018-07-10, 1397/04/19

##### 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

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of effect of Accelerated and Standard Corneal Cross-linking in Down Syndrome keratoconic patients: A Randomized Clinical Trial

## Public title

comparison of 10- and 30-min CXL in Down patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

definite Down syndrome Progressive keratoconus age 10-30 years old minimum cooperation for imaging

### Exclusion criteria:

concurrent intellectual disability such as Autism or Klinefelter History of ophthalmic surgery corneal pathology such as Pterygium

## Age

From **10 years** old to **30 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two eyes of bilateral keratoconic patients

## Randomization (investigator's opinion)

Randomized

## Randomization description

Balanced block randomization by a person other than surgeon

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The patients and parents will be masked to treatment group (10- and 30-min CXL) of each eyes. The optometrist who do the pre- and post-tests will be masked to treatment group (10- and 30-min CXL) of each eyes of patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

None

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

## Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

## Street address

Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.

## City

Tehran

## Province

Tehran

## Postal code

1968653111

## Approval date

2019-03-04, 1397/12/13

## Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.091

## Health conditions studied

### 1

#### Description of health condition studied

Progressive keratoconus in Down syndrome patients

#### ICD-10 code

H19.8

#### ICD-10 code description

Keratoconus in Down syndrome

## Primary outcomes

### 1

#### Description

Corneal biomechanics

#### Timepoint

before and one-year after surgery

#### Method of measurement

Corneal Visualization Scheimpflug Technology (Corvis-ST; Oculus Optikgeräte GmbH, Germany)

### 2

#### Description

corneal keratometry

#### Timepoint

Before and one-year after surgery

#### Method of measurement

Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 10-minutes cross-linking will be perform for one eye of bilateral keratoconic patients under general anesthesia.

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Noor Eye Hospital

**Full name of responsible person**

Soheila Asgari

**Street address**

96, Esfandiar Blvd, Valiasr St.

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**Phone**

+98 21 8240 1621

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**Email**

soheilaasgari@gmail.com

**Web page address**

<http://www.norc.ac.ir/>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Noor Eye Hospital

**Full name of responsible person**

Hassan Hashemi, MD

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**Web page address**

<http://www.norc.ac.ir/>

**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**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Noor Eye Hospital

**Full name of responsible person**

Soheila Asgari

**Position**

no member of review board

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Ophthalmic Research

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Noor Eye Hospital

**Full name of responsible person**

Hassan Hashemi, MD

**Position**

full professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Noor Eye Hospital  
**Full name of responsible person**  
Soheila Asgari  
**Position**  
no member of review board  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Based on demand, only the required part of data is shared unidentifiable.

### When the data will become available and for how long

3 months after publication

### To whom data/document is available

Researcher of Medical and Biomedical engineering  
Universtiy

### Under which criteria data/document could be used

With adhere to the author's copyright of the current project

### From where data/document is obtainable

Sending an academic email to Dr. Soheila Asgari  
"soheilaasgari@gmail.com"

### What processes are involved for a request to access data/document

It is possible to send a request via academic email address, 3 months after publication. The personal profile, data and purpose of study should be mentioned. The ethical approval of study should be sent via email.

### Comments

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