

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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/cm², 10 min) and standard protocol (3 mW/cm², 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Eye Hospital

Full name of responsible person

Soheila Asgari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Noor Eye Hospital

Full name of responsible person

Hassan Hashemi, MD

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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

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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 unidentified.

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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