

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of accelerated and conventional corneal collagen cross-linking for progressive keratoconus in visual acuity, topographic indices, endothelial cell density in one year follow up

#### Protocol summary

##### Summary

purpose of study is Comparison of accelerated and conventional corneal collagen cross-linking for progressive keratoconus in visual acuity, topographic indices, endothelial cell density in one year follow up. study design is interventional, randomized, double blind. samples are between keratoconus patients. if any have other ocular disease or any medical or surgical intervention previous and duration of study or involvement corneal ulcer or any corneal scar are excluded. sample size estimate 72 eyes that are divided equal between two groups. after soaking of cornea with riboflavin irradiated by ultraviolet A. power of Ultraviolet A in one group is used 3 mW/cm<sup>2</sup> in 30 minute and in other group 18 mW/cm<sup>2</sup> in 5 minute. full examination and measuring corrected and uncorrected visual acuity and performing topography, orbscan, specular microscopy are done before and 3, 6, 12 month after treatment in all of patients. thereafter all results are compare.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015080723537N1**

Registration date: **2015-09-06, 1394/06/15**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-06, 1394/06/15

##### Registrant information

##### Name

Seyyed Mohsen Moosazadeh

##### Name of organization / entity

Ahvaz, Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3333 2477

##### Email address

moosazadeh.m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz, Jundishapur University of Medical Sciences

##### Expected recruitment start date

2015-08-16, 1394/05/25

##### Expected recruitment end date

2016-08-14, 1395/05/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of accelerated and conventional corneal collagen cross-linking for progressive keratoconus in visual acuity, topographic indices, endothelial cell density in one year follow up

##### Public title

comparison of accelerated and conventional collagen cross-linking in treatment of keratoconus patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: keratoconus diagnosis based topography and orbscan. exclusion criteria: other ocular diseases; corneal ulcer involvement; surgical

intervention duration study; any corneal scar

### Age

From **12 years** old to **35 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **72**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz, Jundishapur University of Medical Sciences

##### Street address

Ground floor, Vice chancellor for research and technology, Jundishapur University of Medical Sciences, Golestan Avenue, Ahvaz

##### City

Ahvaz

##### Postal code

6135715794

#### Approval date

2015-07-25, 1394/05/03

#### Ethics committee reference number

IR.AJUMS.REC.1394.245

## Health conditions studied

### 1

#### Description of health condition studied

Keratoconus

#### ICD-10 code

H18.6

#### ICD-10 code description

Keratoconus

## Primary outcomes

### 1

#### Description

uncorrected distance visual acuity

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

E chart

### 2

#### Description

corrected distance visual acuity

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

E chart

### 3

#### Description

endothelial cell density

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

specularmicroscopy

### 4

#### Description

endothelial cell hexagonality

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

specularmicroscopy

### 5

#### Description

coefficient of variation

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

specularmicroscopy

### 6

#### Description

spherical equivalent

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

autorefractometer

### 7

#### Description

thinnest point of cornea

#### Timepoint

pre-intervention, 3, 6 and 12 month after intervention

#### Method of measurement

orb scan

## 8

### **Description**

k value in flat meridian

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

orb scan

## 9

### **Description**

k value in steep meridian

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

orb scan

## 10

### **Description**

Kmax

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

orb scan

## 11

### **Description**

keratometry astigmatism value(Kast)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

orb scan

## 12

### **Description**

Surface Asymmetry Index (SAI)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

topography tomy

## 13

### **Description**

Surface Regularity Index (SRI)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

topography tomy

## 14

### **Description**

Keratoconus index (KCI)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

topography tomy

## 15

### **Description**

Keratoconus predication index (KPI)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

topography tomy

## 16

### **Description**

Keratoconus severity index (KSI)

### **Timepoint**

pre-intervention, 3, 6 and 12 month after intervention

### **Method of measurement**

topography tomy

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

conventional corneal cross-linking: soaking cornea with riboflavin 0.1% in 30 minutes then irradiated cornea through ultraviolet A 3 mW/cm<sup>2</sup> in 30 minute.

#### **Category**

Treatment - Surgery

### 2

#### **Description**

accelerated corneal collagen cross-linking: soaking cornea with riboflavin 0.1% in 30 minutes then irradiated cornea through ultraviolet A 18 mW/cm<sup>2</sup> in 5 minute

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital

##### **Full name of responsible person**

Seyyed Mohsen Moosazadeh M.D

##### **Street address**

Eye Ward, Imam Khomeini Hospital, Azadegan Avenue

##### **City**

Ahvaz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Ahvaz, Jundishapur University of Medical Sciences

**Full name of responsible person**

Nader Saki M.D

**Street address**

Ground floor, Vice chancellor for research and technology, Jundishapur University of Medical Sciences, Golestan Avenue, Ahvaz

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz, Jundishapur University of Medical Sciences

**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**

Ahvaz, Jundishapur University of Medical Sciences

**Full name of responsible person**

Seyyed Mohsen Moosazadeh M.D

**Position**

resident of ophthalmology

**Other areas of specialty/work****Street address**

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**Fax****Email**moosazadeh.m@ajums.ac.ir  
aboohashemmousa@gmail.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz, Jundishapur University of Medical Sciences

**Full name of responsible person**

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**Position**

assistant professor

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Ahvaz, Jundishapur University of Medical Sciences

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Seyyed Mohsen Moosazadeh M.D

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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*