

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Continuous-light versus pulsed-light accelerated corneal crosslinking with ultraviolet-A and riboflavin in keratoconus patients

Protocol summary

Study aim

To compare Continuous-light versus pulsed-light accelerated corneal crosslinking with ultraviolet-A and riboflavin in keratoconus patients

Design

Double blinded, parallel group, randomised clinical trial

Settings and conduct

This is a double-blinded-parallel randomised clinical trial to compare continuous-light versus pulsed-light accelerated corneal cross-linking for keratoconus patients in the Ordibehesht hospital and Salouti eye-clinic. The patients, statistician, and staffs for data-gathering will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Progressive keratoconus (Progression of the disease was considered as confirmed if the loss of corrected distance visual acuity (CDVA) was more than one line in 1 year, or when the topographic keratometry increased by >1.0 D in 6 months or >2.0 D in 12 months); The thinnest central corneal thickness (CCT) >400 μm . Non-inclusion criteria: patients who wear contact lenses for one month prior to the initial evaluation and treatment; Patients with immune system disorders; Patient with corneal scar; Patient with history of herpes simplex keratitis; Pregnant or breastfeeding women

Intervention groups

Intervention group 1: (continuous-light accelerated CXL group); Accelerated CXL with continuous-light using 9 mW/cm² for 10 minutes. Intervention group 2: (pulsed-light accelerated CXL group); Accelerated CXL with pulsed on/off light using 9 mW/cm² for 20 minutes. Both irradiation protocols used a commercially available device (UV-360, New Vision, Inc.) with a 5 cm working distance and an 8.0 mm aperture.

Main outcome variables

Best corrected spectacle visual acuity (BSCVA)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190508043529N1**

Registration date: **2019-08-15, 1398/05/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-15, 1398/05/24**

Update count: **0**

Registration date

2019-08-15, 1398/05/24

Registrant information

Name

Ramin salouti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3629 1127

Email address

saloutir@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Continuous-light versus pulsed-light accelerated corneal crosslinking with ultraviolet-A and riboflavin in keratoconus patients		Ethics committee of Shiraz University of Medical Sciences	
Public title	corneal crosslinking in keratoconus patients	Street address	Zand street
Purpose	Treatment	City	Shiraz
Inclusion/Exclusion criteria		Province	Fars
Inclusion criteria:	Progressive keratoconus (Progression of the disease was considered as confirmed if the loss of corrected distance visual acuity (CDVA) was more than one line in 1 year, or when the topographic keratometry increased by >1.0 D in 6 months or >2.0 D in 12 months) The thinnest central corneal thickness (CCT) >400 µm	Postal code	1234567890
Exclusion criteria:	Patients who wear contact lenses for one month prior to the initial evaluation and treatment Patients with immune system disorders Patients with corneal scar Patients with history of herpes simplex keratitis Patients who were pregnant or breastfeeding	Approval date	2019-04-09, 1398/01/20
Age	From 6 years old to 30 years old	Ethics committee reference number	IR.SUMS.REC.1398.241
Gender	Both	Health conditions studied	
Phase	2-3	1	
Groups that have been masked	- Participant - Outcome assessor - Data analyser	Description of health condition studied	
Sample size	Target sample size: 124	Keratoconus	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description	Based on the block-randomization methods with blocks of size 4, patients will be randomly assigned to both intervention groups.	H18.6	
Blinding (investigator's opinion)	Double blinded	ICD-10 code description	
Blinding description	Participants, Statistician, and data collector will be kept blind	Keratoconus	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids	empty	Best corrected spectacle visual acuity (BSCVA)	
Ethics committees		Timepoint	
1		6 months after intervention	
Ethics committee		Method of measurement	
Name of ethics committee		E-chart	
		Secondary outcomes	
		1	
		Description	
		Keratometric indices	
		Timepoint	
		6 months after intervention	
		Method of measurement	
		Pentacam	
		2	
		Description	
		Biomechanical parameters	
		Timepoint	
		6 months after intervention	
		Method of measurement	
		Corvis	
		Intervention groups	

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Description

Intervention group 1: (continuous-light accelerated CXL group); Accelerated CXL with continuous-light using 9 mW/cm² for 10 minutes .

Category

Treatment - Surgery

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Description

Intervention group 2: (pulsed-light accelerated CXL group); Accelerated CXL with pulsed on/off light using 9 mW/cm² for 10 minutes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Salouti eye clinic

Full name of responsible person

Ramin Salouti

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Web page address

<http://www.saloutieyecclinic.com>

2

Recruitment center

Name of recruitment center

Ordibehesht hospital

Full name of responsible person

Ramin Salouti

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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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

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Masihpour

Position

Assistant professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can be achieved upon reasonable request sent to corresponding authors.

When the data will become available and for how long

Starting 2 years after publication

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Data can be achieved upon reasonable request sent to corresponding authors.

From where data/document is obtainable

Department of Ophthalmology, Shiraz University of medical sciences, Dr. Ramin Salouti:
saloutir@hotmail.com

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

Data can be achieved upon reasonable request sent to corresponding authors. Department of Ophthalmology, Shiraz University of medical sciences, Dr. Ramin Salouti:
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Comments