Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 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 wiii 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

Public title
corneal crosslinking in keratoconus patients
Purpose
Treatment
Inclusion/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
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
Age
From **6 years** old to **30 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the block-randomization methods with blocks of size 4, patients will be randomly assigned to both intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, Statistician, and data collector will be kept blind
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand street
City
Shiraz
Province
Fars
Postal code
1234567890
Approval date
2019-04-09, 1398/01/20
Ethics committee reference number
IR.SUMS.REC.1398.241

Health conditions studied

1

Description of health condition studied
Keratoconus
ICD-10 code
H18.6
ICD-10 code description
Keratoconus

Primary outcomes

1

Description
Best corrected spectacle visual acuity (BSCVA)
Timepoint
6 months after intervention
Method of measurement
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

1

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

2

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
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http://www.saloutieyeclinic.com

2

Recruitment center
Name of recruitment center
Ordibehesht hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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Shiraz University of Medical Sciences
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Nasrin Masihpour
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Assistant professor
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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: saloutir@hotmail.com
Comments