Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Long term efficacy of cornea collagen cross-linking (CXL) in Pellucid Marginal Degeneration (PMD) in improving Topographic findings, Visual Acuity (VA) and Refraction

Protocol summary

Study aim
This study is designed to determine whether CXL is helpful for patients diagnosed with PMD in long term or not

Design
A quasi-experimental study, without randomization, not blinded, to be conducted on 40 patients

Settings and conduct
Patients enrolled in this study have underwent CXL in Isfahan Feyz hospital prior to 2015. The study is conducted in Isfahan. The intervention in this study is already done ergo there was no need for randomization and blinding. This study aims to compare keratometric and visual factors of patients before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients that underwent CXL due to mild to moderate PMD before 2015 in Feyz hospital located in Isfahan. Exclusion criteria: inaccessible patient; history of other ophthalmologic surgeries; history of herpetic keratitis prior use of hard contact lens.

Intervention groups
There is only one intervention group in this study, patients that underwent CXL before 2015

Main outcome variables
Topographic findings, Refraction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130306012724N4**
Registration date: **2020-06-04, 1399/03/15**
Registration timing: **prospective**

Last update: **2020-06-04, 1399/03/15**
Update count: **0**

Registration date
2020-06-04, 1399/03/15

Registrant information

Name
Alireza Peyman

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Long term efficacy of cornea collagen cross-linking (CXL) in Pellucid Marginal Degeneration (PMD) in improving Topographic findings, Visual Acuity (VA) and Refraction

Public title
Long term efficacy of cornea collagen cross-linking (CXL) in Pellucid Marginal Degeneration (PMD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients that underwent CXL due to mild to moderate PMD before 2015 in Feyz hospital located in Isfahan

Exclusion criteria:

History of herpetic keratitis Prior use of hard contact lens History of other ophthalmologic surgeries Inaccessible patient

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Science

Street address

Hezar jerib Ave., Isfahan

City

Isfahan

Province

Isfehan

Postal code

81746 73461

Approval date

2020-05-02, 1399/02/13

Ethics committee reference number

IR.MUI.MED.REC.1399.104

Health conditions studied

1

Description of health condition studied

PMD, Pellucid Marginal Degeneration

ICD-10 code

H18.711-71

ICD-10 code description

Pellucid Marginal Degeneration

Primary outcomes

1

Description

Uncorrected Visual Acuity (UCVA)

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Snellen chart

2

Description

Best Corrected Visual Acuity (BCVA)

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Snellen chart

3

Description

K1

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

4

Description

K2

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

5

Description

K max

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

6

Description

Thinnest

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

7

Description

Q value

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

8

Description

Sphere

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

autorefractometry

9

Description

Cylinder

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

autorefractometry

10

Description

ISV

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

11

Description

IVA

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

12

Description

IHA

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

Pentacam topography

13

Description

D

Timepoint

Before intervention, Present time (after at least 5 years from the intervention)

Method of measurement

autorefractometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients that underwent CXL. After total manual debridement of the cornea epithelium, the cornea impregnated with riboflavin using the riboflavin 0.1% + Dextran 20% drops instilled every 2 minutes for 30 minutes; the yellowish glare on slit lamp examination in anterior chamber was utilized to confirm adequate riboflavin penetration to the tissue. The cornea irradiated with ultraviolet A light at 3mW/cm2 and 5.4 j for 30 minutes with a UV light source.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz hospital

Full name of responsible person

Dr. Alireza Peyman

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Modarres St., Ghods Sq., Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjooy Javanmard
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Research dept., Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran
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8174673461
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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Alireza Peyman
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

All researchers who are interested

Under which criteria data/document could be used

Selected researchers

From where data/document is obtainable

Contact principal investigator

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

Maximum one month after contacting the principal investigator

Comments