

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Clinical and Morphological Corneal Changes After Intrastromal Corneal Ring Segment (Keraring) Implantation In Keratoconus Patients

Protocol summary

Summary

Our aim in this study is to evaluate the clinical and morphological corneal changes after intrastromal corneal ring segment (Keraring) implantation in patients with keratoconus. In a unicentral clinical trial, 30 keratoconus patients from both genders referring to clinics of Nikoukari eye Hospital Tabriz, Iran, will be involved for intrastromal corneal ring segment implantation. The key inclusion criteria are intolerance to hard contact lenses; and to have keratometry less than 70 diopters. The main inclusion criteria are to suffer from any local or diffused autoimmune disease. Topography would be accomplished by Pentacam device; size, thickness and number of needed rings would be determined based on keratometry, corneal thickness and Keraring tomogram. All the participants will undergo intrastromal corneal ring segment; Keraring (Mediphacos, Belo Horizonte) implantation which is made up of polymethylen acrylate. A radial incision using a diamond knife between two marked arcs will be performed. Mentioned rings then, will be placed through the canal between the arcs in the depth of 80%. Evaluation of the patients in terms of visual acuity and keratometry will be performed before the surgery, 5, 20, 45 days and 3 months after the surgery. Evaluation with Pentacam will be done at least 3 months after the surgery. Then the obtained data will be statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106026695N1**

Registration date: **2013-05-19, 1392/02/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-19, 1392/02/29

Registrant information

Name

Mohammad Mirzaei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 2171

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-03-08, 1391/12/18

Expected recruitment end date

2013-09-09, 1392/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and Morphological Corneal Changes After Intrastromal Corneal Ring Segment (Keraring) Implantation In Keratoconus Patients

Public title

Clinical Effectiveness of A Surgical Method In Keratoconus Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (intolerance to hard contact lenses; to have corneal thickness equal to or more than 400 micrometers in the area of Keraring placing; to have keratometry less than 70 diopters) Exclusion criteria: (to have any local or diffused autoimmune disease)

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

City

Tabriz

Postal code

Approval date

2013-03-05, 1391/12/15

Ethics committee reference number

91176

Health conditions studied

1

Description of health condition studied

Keratoconus

ICD-10 code

H18.6

ICD-10 code description

Keratoconus

Primary outcomes

1

Description

Visual acuity

Timepoint

Before the intervention, 5, 20, 45 days and 3 months after the intervention

Method of measurement

Using Snellen chart

2

Description

Refractive power of cornea

Timepoint

Before the intervention, 5, 20, 45 days and 3 months after the intervention

Method of measurement

Using keratometer

3

Description

Topography

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Using Pentacam device

Secondary outcomes

empty

Intervention groups

1

Description

All the participants will undergo intrastromal corneal ring segment; Keraring (Mediphacos, Belo Horizonte) implantation which is made up of polymethylen acrylate. A radial incision using a diamond knife between two marked arcs will be performed. Mentioned rings then, will be placed through the canal between the arcs in the depth of 80%.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Nikukari Hospital

Full name of responsible person

Amin Najafi

Street address

Clinics ward, Nikukari Hospital, Abbasi St.

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

AliReza Ostad Rahimi

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht Avenue, Daneshgah Square

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Amin Najafi

Position

Ophthalmology resident, student

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Mirzai

Position

Associate professor, Ophthalmologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

General Physician

Other areas of specialty/work

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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