Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 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

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Name of organization / entity
Tabriz University of Medical Sciences
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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

Tabriz

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