

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

###### Email address

mirzaiem@tbzmed.ac.ir

##### 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**

**Street address**

Nikukari Hospital, Abbasi St.

**City**

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**Phone**

+98 41 1655 1332

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Dr\_Najafi84@yahoo.com

**Web page address**

## 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

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Hemmati

**Position**

General Physician

**Other areas of specialty/work**

**Street address**

Emam Reza Hospital, Daneshgah Ave.

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## 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*