

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Outcome of Phakic posterior chamber intraocular lens implantation in patients with keratoconus

Protocol summary

Summary

The aim of this study is to evaluate the outcome of Phakic posterior chamber intraocular lens implantation in patients with keratoconus. 20 keratoconus patients referring to Nikoukari hospital, Tabriz, Iran, will be involved in a unicentral clinical trial and chosen to undergo a Collamer ICL Phakic posterior chamber lens implantation surgery. The corrected and uncorrected visual acuity together with the refractive error would be measured before surgery and 6 months after surgery to be compared to see if this operation might be as a treatment option for such patients. The key inclusion criteria are to have keratoconus; more than 4 diopter myopia and intolerance to contact lenses while the key exclusion criteria would be to have history of cataract; prior intraocular surgery; retinopathy; glaucoma; retinal detachment and other surgical interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012063010143N1**
Registration date: **2012-07-09, 1391/04/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-09, 1391/04/19

Registrant information

Name

Tahmineh Aryan

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3655 8124

Email address

afshin_lotfi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-05-09, 1391/02/20

Expected recruitment end date

2012-11-10, 1391/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Outcome of Phakic posterior chamber intraocular lens implantation in patients with keratoconus

Public title

Intraocular lens implantation in keratoconus patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having keratoconus; more than 4 diopter myopia; clarity of cornea; anterior chamber depth more than 3mm; number of endothelial cells more than 2000; intolerance to contact lenses. Exclusion criteria: history of cataract; prior intraocular surgery; retinopathy; glaucoma; retinal detachment and other surgical interventions.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

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

Vice cancellor for research, Tabriz University of Medical Sciences, Daneshgah square

City

Tabriz

Postal code

Approval date

2012-05-04, 1391/02/15

Ethics committee reference number

9152

Health conditions studied

1

Description of health condition studied

Keratoconus

ICD-10 code

H18.6

ICD-10 code description

Keratoconus

Primary outcomes

1

Description

Uncorrected visuak acuity

Timepoint

Before and 6 months after surgery

Method of measurement

Using LogMAR

2

Description

Corrected visual acuity

Timepoint

Before and 6 months after surgery

Method of measurement

Using LogMAR

3

Description

Refractive error

Timepoint

Before and 6 months after surgery

Method of measurement

Using Spherical equivalent

Secondary outcomes

empty

Intervention groups

1

Description

All individuals involved in this study will undergo a Collamer ICL Phakic posterior chamber lens implantation surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikoukari hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostad Rahimi

Street address

Vice cancellor for research, Tabriz University of Medical Sciences, Daneshgah square

City

Tabriza

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

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

Mohammadreza Neusha

Position

MD, Ophthalmology resident

Other areas of specialty/work**Street address**

Nikoukari hospital, Abbasi avenue

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Mohammadreza Neusha

Position

MD, Ophthalmology resident

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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