

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 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 Siences, 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 chancellor for research, Tabriz University of Medical Siences, 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**

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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Assistant Professor, Ophthalmologist

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

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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