

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### comparison of wavefront-guided and cross-cylinder photorefractive keratectomy in correcting medium-high astigmatism

#### Protocol summary

##### Summary

The aim of this study is to compare the visual and refractive results of wavefront-guided and cross-cylinder photorefractive keratectomy by visx and nidek laser systems in correcting medium-high astigmatism. 50 eyes of 25 patients with stable refraction are randomly selected for wavefront-guided photorefractive keratectomy between December 2009 and December 2010. Then the results will be compared with findings of 48 patients who had been previously operated by cross-cylinder approach two years ago. Patients with pachymetry less than 470 microns are excluded. Correction of astigmatism is the primary outcome.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902083827N1**

Registration date: **2009-11-22, 1388/09/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-11-22, 1388/09/01

##### Registrant information

###### Name

Mohammad Reza Sedghipour

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1330 6619

###### Email address

sedghipm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2009-11-22, 1388/09/01

##### Expected recruitment end date

2010-11-22, 1389/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of wavefront-guided and cross-cylinder photorefractive keratectomy in correcting medium-high astigmatism

##### Public title

Comparison of wavefront-guided and cross-cylinder photorefractive keratectomy in correcting medium-high astigmatism

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: stable refraction, astigmatism more than 1.50 diopter, age 20-50 years Exclusion criteria: any ocular pathology, pachymetry less than 470 micron, connective tissue disease, asymmetric astigmatism, tear film abnormality

##### Age

From **20 years** old to **50 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

## Sample size

Target sample size: **98**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Gholghasht street

##### City

Tabriz

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

3099/4/5

## Health conditions studied

### 1

#### Description of health condition studied

medium-high astigmatism

#### ICD-10 code

H52

#### ICD-10 code description

Disorders of refraction

## Primary outcomes

### 1

#### Description

correction of astigmatism

#### Timepoint

preoperative and six months postoperative

#### Method of measurement

refraction

## Secondary outcomes

### 1

#### Description

visual acuity

#### Timepoint

preoperative and six months postoperative

#### Method of measurement

snellen chart

### 2

#### Description

visual aberrations

#### Timepoint

preoperative and six months postoperative

#### Method of measurement

aberrometry

## Intervention groups

### 1

#### Description

wavefront-guided photorefractive keratectomy

#### Category

Treatment - Surgery

### 2

#### Description

cross-cylinder photorefractive keratectomy

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nikookari Hospital

##### Full name of responsible person

Rana Sorkhabi,MD

##### Street address

Abbasi avenue

##### City

Tabriz

### 2

#### Recruitment center

##### Name of recruitment center

Mehr Hospital

##### Full name of responsible person

Mohammad Reza Sedghipour,MD

##### Street address

Taleghani street

##### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Research Secretary, Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Rashidi

**Street address**

Gholghasht street, second central building, Tabriz University of Medical Sciences

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Secretary, 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**

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Associate Professor

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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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*