

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Corneal astigmatism & wavefront aberration changes after cataract surgery: single clear corneal incision versus paired opposite clear corneal incisions

Protocol summary

Summary

Objective: Comparison between effects of single clear corneal incision and paired opposite clear corneal incisions on corneal astigmatism and aberrations after cataract surgery based on wavefront analysis in patients with astigmatism. Key inclusion and exclusion criteria: patients requiring cataract surgery, which is equal to or greater than 1.5 diopters of astigmatism. Preoperative have entered into this study. Any patients with corneal disease such as corneal scar, pterygium, history of corneal surgery for any reason and peri operative complications should be excluded. Study population: patients with cataract referred to Feiz Hospital, Isfahan, and astigmatism are more than 1.5 diopters. Sample size: 50 patients (25 patients in each group). Intervention Study: Patients are randomly assigned in two groups: single clear corneal incision and paired opposite clear corneal incisions. Standard cataract surgery with these incisions will be done. Time: MARCH 2011-JAN 2013; Feiz hospital, Isfahan, Iran. Primary outcome: keratometric astigmatism and optical aberrations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031712833N1**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

Name

Nima Koosha

Name of organization / entity

Isfahan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1776 8475

Email address

koosha@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University Of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Corneal astigmatism & wavefront aberration changes after cataract surgery: single clear corneal incision versus paired opposite clear corneal incisions

Public title

Effect of corneal incision in cataract surgery on astigmatism and optical aberrations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with cataract ; Corneal astigmatism greater than 1.5 diopter Exclusion: Any other

corneal pathology; Corneal scar; Pteregium; History of previous corneal surgery; Peri operative complication.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University Of Medical Sciences

Street address

Daneshgah Ave

City

Isfahan

Postal code

Approval date

2011-10-19, 1390/07/27

Ethics committee reference number

391296

Health conditions studied

1

Description of health condition studied

corneal astigmatism and aberrations

ICD-10 code

H 52.2,

ICD-10 code description

Disorders of ocular muscles, binocular movement, accommodation and refraction,

Primary outcomes

1

Description

Keratometric astigmatism

Timepoint

Preoperation and 3 months postoperation

Method of measurement

Keratometry

2

Description

Optical aberrations

Timepoint

Preoperation and 3 months post operation

Method of measurement

Wavefront

Secondary outcomes

empty

Intervention groups

1

Description

Control group:Single clear corneal incision on steep meridian

Category

Treatment - Surgery

2

Description

Intervention group:Paired opposite clear corneal incisions on steep meridian

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz Hospital

Full name of responsible person

Dr.Hasan Razmjoo

Street address

Qhods Sq, Modarres St

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Dr Hasan Razmjoo

Street address

Daneshgah Ave

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University Of Medical Sciences

Full name of responsible person

Nima Koosha

Position

Resident of Ophthalmology

Other areas of specialty/work

Street address

Num 118, Shahid soleymani st. Farhang st ,Simin st

City

Isfahan

Postal code

8177784311

Phone

+98 31 1776 8475

Fax

Email

koosha@resident.mui.ac.ir n_koosha@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University Of Medical Sciences

Full name of responsible person

Nima Koosha

Position

Resident of Ophthalmology

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Street address

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Person responsible for updating data

Contact

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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