

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of clinical outcome between Wavefront-optimized photorefractive Keratectomy and Wavefront-guided photorefractive Keratectomy in patients with Astigmatism higher than 2 diopters

Protocol summary

Study aim

The purpose of study is to determine the clinical outcome of wavefront optimized photorefractive keratectomy (WO-PRK) and wavefront guided photorefractive keratectomy (WG- PRK) in patients with astigmatism refractive error higher than two diopters .

Design

This study is a randomized controlled clinical trial with parallel groups. 206 patients with astigmatism refractive error higher than 2 diopters are divided to two equal groups by Random allocation software

Settings and conduct

206 patients with astigmatism higher than 2 diopters that apply Feiz hospital in Isfahan are divided to two groups. WO-PRK will be done for the first group and WG-PRK will be done for the second group. After six months aberration number, visual acuity , contrast sensitivity and refractive error will be evaluated and will be analyzed with SPSS version 25.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with Astigmatism higher than 2 D refractive error ; Best-corrected visual acuity (BCVA) of 20/20 or better in both eyes ; Age 21 years or older
Exclusion Criteria : Ocular surface disease ; Recent Use of rigid gas-permeable contact lens Corneal disease and cataract ; Previous intraocular or corneal surgery ; A history of herpetic keratitis ; Current use of systemic immunosuppressive therapy ; presence of clinically significant atopic disease ; Connective tissue disease ; History of Glaucoma ; macular disease ; pregnancy or lactation

Intervention groups

WO-PRK will be done for the first group and WG-PRK will be done for the second group.

Main outcome variables

Refractive Error; Aberration number; Contrast Sensitivity; Visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044459N1**

Registration date: **2019-09-27, 1398/07/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-27, 1398/07/05**

Update count: **0**

Registration date

2019-09-27, 1398/07/05

Registrant information

Name

Saeedreza Moshfeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3626 5804

Email address

moshfeghi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcome between Wavefront-optimized photorefractive Keratectomy and Wavefront-guided photorefractive Keratectomy in patients with Astigmatism higher than 2 diopters

Public title

The effect of different techniques of PRK surgery on astigmatism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Astigmatism higher than 2 D refractive error Best-corrected visual acuity (BCVA) of 20/20 or better in both eyes Age 21 years or older

Exclusion criteria:

Dissatisfaction for participation Ocular surface disease and corneal dystrophy Recent use of Rigid Contact Lens (RGP) Previous corneal or intra-ocular surgery History of herpes keratitis Current use of systemic immunosuppressive therapy Presence of clinically significant atopic disease Connective tissue disease macular disease History of Glaucoma pregnancy and lactation

Age

From **21 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **206**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each eye of a patient is considered a distinct sample.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done with Random Allocation software.

Blinding (investigator's opinion)

Not 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

Qods square - Feiz hospital

City

Isfahan

Province

Isfahan

Postal code

1234512345

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.MUI.MED.REC.1398.047

Health conditions studied

1

Description of health condition studied

Astigmatism

ICD-10 code

H52.223

ICD-10 code description

Regular astigmatism, bilateral

Primary outcomes

1

Description

Visual acuity

Timepoint

Before Surgery , 6 Months after surgery

Method of measurement

snellen chart

2

Description

Contrast Sensitivity

Timepoint

6 months after surgery

Method of measurement

CSV-1000 Chart

3

Description

Aberration Number

Timepoint

Before surgery ,6 Months after surgery

Method of measurement

Aberrometer

4

Description

Refractive Error

Timepoint

Before Surgery , 6 Months after Surgery

Method of measurement

Auto Refractometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with Astigmatism Refractive Error Higher than 2 diopters that undergo Wave front optimized Photorefractive Keratectomy

Category

Treatment - Surgery

2

Description

Intervention group: Patients with Astigmatism Refractive Error Higher than 2 diopters that undergo Wave front Guided Photorefractive Keratectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz hospital

Full name of responsible person

Saeedreza Moshfeghi

Street address

Feiz Hospital , Qods Square

City

Isfahan

Province

Isfahan

Postal code

8149644874

Phone

+98 31 3445 2031

Email

moshfeghi69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences , Hezar jarib St

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Saeedreza Moshfeghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All the study database will be accessible except the participants personal data.

When the data will become available and for how long

The database will be accessible 6 months after result publication.

To whom data/document is available

The database will be accessible for academic researchers

Under which criteria data/document could be used

Use of database in academic researches is permitted by reference to the source.

From where data/document is obtainable

For database access , the request must be sent to moshfeghi69@gmail.com

What processes are involved for a request to access data/document

Upon sending an email, the request will be reviewed by the Hospital Research Center and will be sent to the applicant's academic research center immediately after verification of the identity.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Saeedreza Moshfeghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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