Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 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
Isfehan
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
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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
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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 updating data

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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