Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of asymmetric offset versus pupil centered ablation in refractive surgery

Protocol summary

Study aim
To compare the visual and optical outcomes following femtosecond laser in situ keratomileusis (FS-LASIK) with asymmetric offset (AO) and pupil centered (PC) treatments

Design
Randomized clinical trial with concealed allocation, 2 parallel group and double blinded

Settings and conduct
In Noor Eye hospital, a total of 60 FS-LASIK candidates who meet the study criteria will be undergone hyperopic astigmatism (30 cases) and myopic astigmatism (30 cases) LASIK using the Schwind Amaris 1050 excimer laser platform, respectively. One eye of each individual will be randomly assigned to AO centration and the fellow eye will be undergone the PC-centered method. Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), safety and efficacy indexes, subjective refraction and corneal aberrations will be measured at baseline and 6 months postoperatively. Neither the patients nor the examiners will be aware of the assigned eyes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: FS-LASIK candidates in following range: Age: 18-60 years Spherical Equivalent (SE): +400 to -6.00 Diopter Corrected distance visual acuity (CDVA): 9/10 or better HOA (higher order aberration) < 0.65 µm Pupil to vertex offset values ≥ 0.2 mm Exclusion criteria: A history of any ocular surgery Systematic diseases such as thyroid disease or diabetes Presence of cataract Glaucoma or intraocular pressure (IOP) > 21 mmHg Any corneal irregularity or opacity Any posterior segment disorders Pregnancy or breastfeeding

Intervention groups
One eye of each individual will be randomly assigned to AO centration and the fellow eye will be undergone the PC-centered method

Main outcome variables
Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), safety and efficacy indexes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180428039441N2**
Registration date: **2023-01-17, 1401/10/27**
Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**
Update count: **0**

Registration date
2023-01-17, 1401/10/27

Registrant information
Name
Mojgan Pakbin
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8240 1675
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m_pakbin@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-09, 1401/11/20

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of asymmetric offset versus pupil centered ablation in refractive surgery

Public title
Centration in refractive surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Femto-LASIK candidates in following criteria Age: 18-60 years Spherical Equivalent (SE): +400 to -6.00 Diopter Corrected distance visual acuity (CDVA): 9/10 or better HOA (higher order aberration) < 0.65 µm Pupil offset ≥ 0.2 mm (200 µm) Steady refractive errors (change < 0.5 diopter) during a year before Femto-LASIK Discontinuing soft contact lens and hard contact lens 1 and 4 weeks before the first examination, respectively

Exclusion criteria:
A history of any ocular surgery Systematic diseases such as thyroid disease or diabetes Presence of cataract Glaucoma or intraocular pressure (IOP) > 21 mmHg Any corneal irregularity or opacity Any posterior segment disorders Pregnancy or breastfeeding

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
In this study, one eye of each individual will be randomly assigned to AO centration and the fellow eye will be undergone the PC-centered method

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, there will be two types of surgical methods, A and B, which represent Asymmetric offset and Pupil center, respectively. In each individual, the right eye will be randomly operated with one of these two methods and the opposite eye will be operated with another method. Balanced block randomization method will be used for random assignment of surgical procedure. This method will prevent any prediction of the order of intervention. The entire process of random assignment will be done by STATA software using the ralloc package. After determining the blocks with a size of 4, the type of treatment (A or B) specified by the software will determine the surgery method of the right eye, and the opposite eye will be operated by another method. For example, A, indicates that the right eye will be operated by the Asymmetric offset treatment and the left eye by the Pupil center method. It should be noted that, in order to the allocation concealment, the surgical method of each patient will be placed in a sealed envelope with a unique random code generated by the software. This ensures that the surgeon will be noticed the random sequence only when the envelope is opened.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are unaware of which eye is in the control or intervention group. Also, those who perform the tests (optometrist and the clinical ophthalmologist responsible for ocular examination) will also be unaware of which eye (intervention or placebo) is evaluating

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
University Central Building,Ghods St, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1417733161

Approval date
2022-12-19, 1401/09/28

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.613

Health conditions studied

1

Description of health condition studied
Centration of ablation profile in refractive surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Uncorrected distance visual acuity (UDVA)

Timepoint
Before and 6 months after surgery
Method of measurement
Snellen Chart

2

Description
Corrected distance visual acuity (CDVA)
Timepoint
Before and 6 months after surgery
Method of measurement
Trial frame, Snellen Chart

3

Description
Safety index
Timepoint
6 months after surgery
Method of measurement
Calculation based on UDVA

4

Description
Efficacy index
Timepoint
6 months after surgery
Method of measurement
Calculation based on UDVA and CDVA

Secondary outcomes

1

Description
Refraction
Timepoint
Before and 6 months after surgery
Method of measurement
Auto-refractometer, trial frame, Snellen chart

2

Description
Corneal Aberrations
Timepoint
Before and 6 months after surgery
Method of measurement
Pentacam

Intervention groups

1

Description
Intervention group: After local anesthesia, a flap (110 µm thick) is created using a Femto LDV (Ziemer Ophthalmic Systems AG, Port, Switzerland). After flap removal, ablation is performed using AMARIS 1050RS (SCHWIND, Munich, Germany) with asymmetric offset centering. After the operation, chloramphenicol 0.5% Sina Daro drops will be prescribed 4 times a day for 3 days and betamethasone 0.1% Sina Daro 4 times a day for one week.
Category
Treatment - Surgery

2

Description
Control group: After local anesthesia, a flap (110 µm thick) is created using a Femto LDV (Ziemer Ophthalmic Systems AG, Port, Switzerland). After flap removal, ablation is performed using AMARIS 1050RS (SCHWIND, Munich, Germany) with pupil center treatment. After the operation, chloramphenicol 0.5% Sina Daro drops will be prescribed 4 times a day for 3 days and betamethasone 0.1% Sina Daro 4 times a day for one week.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Eye Hospital
Full name of responsible person
Mojgan Pakbin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
NOOR Eye Hospital
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
NOOR Eye Hospital
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
NOOR EYE Hospital
Full name of responsible person
Mojgan Pakbin
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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Researcher
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Per request, we will decide about the dissemination of the data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary

Not applicable