

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 μ m Pupil to vertex offset values $\geq$ 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

Email address

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 μ m Pupil offset $\geq$ 0.2 mm (200 μ m) 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**

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Full name of responsible person

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research@norc.ac.ir

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
Optometry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Hassan Hashemi

Position
Professor, Ophthalmology Department, Tehran University of Medical Sciences, Tehran, Iran

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Subspecialist

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Ophthalmology

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Person responsible for updating data

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Ph.D.

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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