Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Effect of eye-tracker system in FS-LASIK on optical zone centration: a contralateral randomized clinical trial

Protocol summary

Study aim
To investigate the effect of eye-tracker system on ablation zone centration after femtosecond-assisted laser in situ keratomileusis (FS-LASIK) in myopic patients.

Design
Randomised, contralateral, parallel group trial with blinded outcome assessment on 70 biletral myopic patients. Randomisation was done with balanced block pattern in block size of 2 on the right of each patients.

Settings and conduct
In this trial, 70 myopic patients aged 20 to 45 years with myopia ≥ 3.0 D, who are candidates for femtosecond-assisted laser in situ keratomileusis (FS-LASIK) enroll in Noor Eye Hospital. Ophthalmic examination and pentacam imaging will be performed at baseline and 3 months after surgery. Topographic centration of the treatment zone is defined as offset from corneal vertex in X-coordinate, Y-coordinate, and vector distance and compare between two groups after adjusting the correlation between two eyes. The effect of decentration on change in vision, refraction and postoperative higher order abberations (HOA) will be assessed.

Participants/Inclusion and exclusion criteria
Patients with: - age 20 to 45 years of both gender - myopia≥ 3.0 D - stable refraction in the past year (change ± 0.50 D or less) - RSB of at least 300.0 µm - without ectasia sign

Intervention groups
Patients with bilateral myopia will be entered the study. One eye of each patient is allocated in the eye-tracker group and the other eye is placed in the control group (without using eye-tracker).

Main outcome variables
-Decentration in X-coordinate and Y-coordinate - Vectorial distance from corneal vertex - Study groups - Vision, refraction, and aberrations

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100706004333N4**
Registration date: **2021-11-22, 1400/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-22, 1400/09/01**
Update count: **0**

Registration date
2021-11-22, 1400/09/01

Registrant information
Name
Soheila Asgari
Name of organization / entity
Noor eye hospital
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-02-19, 1400/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of eye-tracker system in FS-LASIK on optical zone centration: a contralateral randomized clinical trial

Public title
Comparison of manual and automatic laser ablation in feto-LASIK

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
myopia≥ 3.0D stable refraction in the past year (change ± 0.50 D or less) residual stromal bed thickness (RSB) of at least 300.0 µm

Exclusion criteria:
Corneal ectasia

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this contralateral clinical trial, two eyes of each patients randomly allocated in each study group by balanced block randomization (BBR) to achieve a best power in the analysis. BBR is used in a block size of 2 on the right eye of each patient. With this method, sequencing of eye-tracker and manual cods of right eye is detremined by a table of randome number and binary blocks. In this way, one eye of each patient will be allocated in the eye-tracker group and the other eye in the control group (without using eye-tracker). To concealment, randomization is performed by a non-surgeon. The technician was informed about the allocated group of each eyes at the time of surgery. The surgeon will be masked to the groups until to surgery time.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patints are masekd to the groups until the end of study. The surgeon is masked to each eye patient group until surgery. Also statistician and ophthalmic healthcare providers are masked to the treatment allocation of each eye.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address
Faculty of medicine, Poursina Ave., Qods Ave., Enqelab Ave.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2021-10-27, 1400/08/05

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.820

Health conditions studied

1

Description of health condition studied
Myopia

ICD-10 code
H52.13

ICD-10 code description
Myopia, bilateral

Primary outcomes

1

Description
Decentration of ablation zone from corneal vertex

Timepoint
3 months after surgery

Method of measurement
Pachymetric map by Pentacam

Secondary outcomes

1

Description
visual acuity

Timepoint
3 months after surgery

Method of measurement
Snellen chart

2

Description

Refraction

Timepoint

3 months after surgery

Method of measurement

Retinoscope

3

Description

corneal aberrations

Timepoint

3 months after surgery

Method of measurement

Pentacam

Intervention groups

1

Description

In femtosecond assisted laser in situ keratomileusis (FS-LASIK), after topical anesthesia, the flap (110.0 µm thick) is created by Femto LDV (Ziemer Ophthalmic Systems AG, Port, Switzerland). After flap lift, wavefront-optimized ablation is performed using AMARIS 1050RS (SCHWIND, Munich, Germany). The optical zone is 6.5 mm for moderate myopia, 6.0 mm for high myopia, and blend zone was 1.25 mm for all cases. Based on the random groups of each eye, the eye-tracker is turned on (with eye-tracker) and off (without eye-tracker) by the device engineer during ablation. Postoperative treatment regimen includes chloramphenicol eye drop 0.5% (Sina Darou, Tehran, Iran) every 6 hours to 3 days and betamethasone 0.1% eye drops (Sina Darou, Tehran, Iran) every 6 hours to 7 days.

Category

Treatment - Surgery

2

Description

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Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Eye Hospital

Full name of responsible person

Hassan Hashemi, MD

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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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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

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Noor Eye Hospital

Full name of responsible person
Soheila Asgari

Position
Research assistant

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The anonymous data will be available in case of reasonable request by corresponding author.

When the data will become available and for how long
6 months after publication

To whom data/document is available
A member of a scientific board

Under which criteria data/document could be used
For clinical or research utilization

From where data/document is obtainable
Sending an email to the corresponding author / Hassan Hashemi (research@norc.ac.ir) Sending an email to the co-author / Soheila Asgari (soheilaasgari@gmail.com)

What processes are involved for a request to access data/document
Sending name and affiliation through an academic email

Comments