

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of conventional and transepithelial photorefractive keratectomy in myopic and myopic astigmatism patients

Protocol summary

Study aim

Comparison of conventional and transepithelial methods of epithelial debridement in photorefractive keratectomy in terms of postoperative recovery rate

Design

Randomized clinical trial, 2 parallel and double-blinded groups

Settings and conduct

Patients with myopia and myopia astigmatism candidates for PRK using the Amaris eximer laser at Noor eye Hospital will be randomly assigned to one of two intervention groups using a randomization blocks table. Epithelial defect imaging will be performed on the day of surgery immediately following the surgery, and on consecutive days after surgery until wound healing. Epithelial defect area in each image will be calculated using an image processing software. Also, on postoperative day 1, 3 and 7, a standardized questionnaire will be used to assess pain severity and symptoms in each eye. Three months later, the patient is examined for visual acuity, refraction, and haze.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age between 18 to 50 years; equivalent sphere at least -2.00 diopter with astigmatism up to -4.00 diopter and myopia up to -8.00 diopter; stability of refraction for at least one year before surgery; corrected visual acuity more than 20/30. Contact lens use should be discontinued at least 3 weeks prior to surgery. Exclusion criteria include any eye pathology including corneal dystrophy, keratoconus or keratoconus suspect, glaucoma or glaucoma suspect; and a history of diabetes, autoimmune diseases and any previous ophthalmic surgery.

Intervention groups

Group 1: One eye is operated by Trans PRK and the other one by Mechanical PRK Group 2: One eye is operated by Trans PRK and the other by Alcohol-assisted PRK

Main outcome variables

The healing rate of corneal epithelial defect

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046804N1**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

Azam Alvani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of conventional and transepithelial photorefractive keratectomy in myopic and myopic astigmatism patients		Parallel
Public title Conventional and transepithelial PRK		Other design features
Purpose Treatment		Secondary Ids empty
Inclusion/Exclusion criteria Inclusion criteria: Equivalent sphere at least -2.00 diopter with astigmatism up to -4.00 diopter and myopia up to -8.00 diopter. The stability of refraction for at least one year before surgery. Corrected visual acuity more than 20/30. Contact lens use should be discontinued at least 3 weeks prior to surgery. age between 18 to 50 years Exclusion criteria: Any ocular pathology including corneal dystrophy, keratoconus or keratoconus suspect and glaucoma or glaucoma suspect. The history of diabetes and autoimmune diseases. The history of any previous ocular surgery.		Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Tehran University of Medical Sciences Street address Central Building of the University, Quds Street, Keshavarz Boulevard City Tehran Province Tehran Postal code 1417733161 Approval date 2020-04-30, 1399/02/11 Ethics committee reference number IR.TUMS.MEDICINE.REC.1399.033
Age From 18 years old to 50 years old		Health conditions studied 1 Description of health condition studied Corneal epithelium debridement in Photorefractive keratectomy ICD-10 code H17.8 ICD-10 code description Other corneal scars and opacities
Gender Both		Primary outcomes 1 Description Corneal epithelial defect size Timepoint Day of operation and consecutive days after surgery until complete healing of corneal epithelial defect (at least 3 and up to 7 days) Method of measurement Using photoslit
Phase N/A		Secondary outcomes 1 Description Severity of patient's pain and discomfort due to corneal epithelial defect
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 Both eyes of patients with bilateral myopia and/or myopic astigmatism.		
Randomization (investigator's opinion) Randomized		
Randomization description The randomization will be done using permuted-block randomization method and based on a block size of 4. The random sequence of blocks will be obtained from the random number table. In the first stage, patients will be assigned to one of the two intervention groups A and B, and in the second stage, it will be randomized to determine which eye will be operated on by transepithelial method. Allocation concealment will be performed by sequentially numbered, sealed, opaque envelopes.		
Blinding (investigator's opinion) Double blinded		
Blinding description Patients are unaware of which group they are in. People who do the tests (optometrist and clinical ophthalmologist) will also be unaware of which intervention group they are evaluating.		
Placebo Not used		
Assignment		

Timepoint

Consecutive days after surgery until complete healing of corneal epithelial defect (at least 3 and up to 7 days)

Method of measurement

11-Point numeric scale of pain Questionnaire and Eye sensation scale Questionnaire

2**Description**

Non-corrected and corrected VA

Timepoint

Preoperation and 3 month after operation

Method of measurement

Snellen Chart

3**Description**

Refraction

Timepoint

Preoperation and 3 month after operation

Method of measurement

Autorefractometer

Intervention groups**1****Description**

Intervention group 1: Both patient's eyes underwent photorefractive keratectomy, but the method of corneal epithelial removal is different. In one eye, the epithelium is removed mechanically by the surgeon, and in the other eye, it is done by excimer laser device without the intervention of the surgeon's hand.

Category

Treatment - Surgery

2**Description**

Intervention group 2: Both patient's eyes underwent photorefractive keratectomy, but the method of corneal epithelial removal is different. In one eye, the epithelium is removed using alcohol and by the surgeon, and in the other eye, it is done by excimer laser device without the intervention of the surgeon's hand.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Noor Eye Hospital

Full name of responsible person

Azam Alvani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Noor Eye Hospital

Full name of responsible person

Dr. Seyed Hasan Hashemi

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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

Azam Alvani

Position

PhD student of ophthalmology clinical sciences

Latest degree

Master

Other areas of specialty/work

Optometrist

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

Noor Eye Hospital

Full name of responsible person

Azam Alvani

Position

PhD student of Ophthalmology Clinical Sciences

Latest degree

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Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Dr. Seyed Hasan Hashemi

Position

Professor

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Subspecialist

Other areas of specialty/work

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Email**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

There are no more information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable