Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 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

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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

Public title
Conventional and transepithelial PRK
Purpose
Treatment
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.
Age
From **18 years** old to **50 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**
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 envelopesa.
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
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
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

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

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

Secondary outcomes

1

Description
Severity of patient's pain and discomfort due to corneal epithelial defect

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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No. 96, Esfandiar Blvd, Valiasr Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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