Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 2026

Comparison of moderate to high myopic astigmatism correction using PRK and transepithelial PRK

Protocol summary

Study aim
Comparison of moderate to high myopic astigmatism correction using PRK and transepithelial PRK

Design
The present study is a clinical trial study The sampling method in the present study is available in a non-random way, so that the eligible people will be selected until the required sample size is reached. The selection of people to treatment groups in the present study will be random assignment. The sample size in this study was calculated based on the result of refraction changes based on the actual findings of Zarei et al.'s study (20) with the number of 32 eyes and including the loss of 35 eyes in each group. In each person, one eye becomes PRK and the other eye becomes TRANS PRK There are two study groups. A group of eyes that undergo prk surgery and a group that undergo trans prk surgery and different outcomes between them are examined.

Settings and conduct
noor afarin eye clinic

Participants/Inclusion and exclusion criteria
Patients with astigmatism of 2 diopters and more, as well as patients with myopia between minus 2 and minus 6, and the patient must have informed consent to participate in the study

Intervention groups
PRK TRANS PRK In this study, in each person, one eye is subjected to prk surgery and the other eye is subjected to trans prk surgery (the method of selection is random, the method of which is explained), and in fact, the eyes are divided into two groups, the group that is under prk operation and the group that underwent trans prk operation and the results are checked in them

Main outcome variables
BCVA (best corrected visual acuity) ، UCVA (uncorrected visual acuity) ، epithelial map و High order aberration . astigmatism

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230124057199N1**
Registration date: **2023-08-05, 1402/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-05, 1402/05/14**
Update count: **0**

Registration date
2023-08-05, 1402/05/14

Registrant information
Name
ehsan salar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3603 5069
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ehsan.salar@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-05-30, 1402/03/09
Expected recruitment end date
2024-05-29, 1403/03/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of moderate to high myopic astigmatism correction using PRK and transepithelial PRK

Public title
Comparison of moderate to high myopic astigmatism correction using PRK and transepithelial PRK
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient has informed consent to participate in the study Patients with myopia between -2 and -6 Patients with astigmatism of 2 diopters and more
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization A lottery method is used for randomization. In this way, two completely folded papers are placed in a container (in such a way that the contents of the paper are not visible from the outside). The left eye is written on one paper and the right eye is written on the other paper. In another container, two folded papers are placed. PRK is written on one paper and trans PRK is written on the other paper for the patient who has written informed consent to participate. He signs the study, after mixing, he takes a piece of paper from each container, according to the contents of the paper, surgery will be performed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient is not told which eye is prk and which is trans A researcher who sees the patient in the follow-ups and examines various items in each eye does not know which eye is prk and which eye is trans.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Mashhad university of medical Sciences
Street address
Khatam hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9981747434
Approval date
2022-11-19, 1401/08/28
Ethics committee reference number
IR.MUMS.REC.1401.305

Health conditions studied

1

Description of health condition studied
moderate to high myopic astigmatism
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
UCVA (uncorrected visual acuity)
Timepoint
The end of the first, third and sixth months
Method of measurement
snellen chart

2

Description
BCVA (best corrected visual acuity)
Timepoint
The end of the first, third and sixth months
Method of measurement
snellen chart

3

Description
Comparison of high order aberration changes
Timepoint
The end of the first, third and sixth months
Method of measurement
aberrometry

4

Description
Changes in the epithelial map
Timepoint
The end of the first, third and sixth months

Method of measurement
corneal oct with casia ii

5

Description
Astigmatism correction
Timepoint
The end of the first, third and sixth months
Method of measurement
Auto refractometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: PRK PRK is an eye surgery that improves vision by correcting refractive errors such as astigmatism, nearsightedness, and farsightedness.In PRK surgery, the surgeon removes a very thin layer of the corneal tissue, the epithelium, to access the underlying tissue. The surgeon does this manually using an alcohol solution and a fine surgical knife. The next stage in the PRK operation, the surgeon uses a laser to correct the surface of the cornea at certain pre-planned points. The epithelial tissue that was initially removed will repair itself over the next few days
Category
Treatment - Surgery

2

Description
Intervention group: TRANS PRK In the Trans-PRK method, or the No-Touch method, the surface layer (corneal epithelium) is removed with a laser instead of using tools and manually.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Nour Afarin eye clinic
Full name of responsible person
dr Siamak Zarei Ghanavati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Siamak Zarei Ghanavati
Position
Professor
Latest degree
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Ophthalmology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available