Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of mitomycin C on higher order aberrations in low and moderate myopic (astigmatic) PRK

Protocol summary

Summary

This study is performed in order to assess the effect of Mitomycin C in high order aberration in low to moderate myopic astigmatic PRK Surgery. 130 eyes from the patients meeting eligibility criteria are assigned to receive a single drop of Mitomycin C, 0.02 % eye drop or normal saline at the end of surgery. The patients will be visited at 4th week and 6th month after the surgery. Refraction, aberrometry, and slit lamp findings are recorded and results of high order aberration and corneal hysteresis are compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008094537N1**
Registration date: **2011-01-24, 1389/11/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-01-24, 1389/11/04

Registrant information

Name
Seyed-Farzad Mohammadi
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 5542 1010
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sfmohamm@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date

2010-10-10, 1389/07/18

Expected recruitment end date

2011-06-10, 1390/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mitomycin C on higher order aberrations in low and moderate myopic (astigmatic) PRK

Public title

Effect of mitomycin C on higher order aberrations in low and moderate myopic (astigmatic) PRK

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Myopia lower than 4 D (Spherical Eq), Astigmatism lower than 1.87 D Exclusion criteria: Previous eye surgery, Dry eye syndrome, HOA RMS more than 0.3 microns, Anisometropia more than 1.5 D syndrome

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences Ethics Committee
Street address
University Central Building,Ghods St, Keshavarz Blvd.
City
Tehran
Postal code
1417733161
Approval date
2010-10-03, 1389/07/11
Ethics committee reference number
89/d/130/860

Health conditions studied

1

Description of health condition studied
Myopia
ICD-10 code
H52.1
ICD-10 code description
myopia

Primary outcomes

1

Description
higher order aberration
Timepoint
1 month and 6 months
Method of measurement
Wavefront aberrometry by Zywave

Secondary outcomes

1

Description
Corneal hysteresis
Timepoint
1 month and 6 months
Method of measurement
Ocular Response Analyzer

Intervention groups

1

Description
Mitomycin C dosage 0.02% one drop in the end of surgery
Category
Treatment - Drugs

2

Description
Normal saline one drop in the end of surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Eye Hospital
Full name of responsible person
S-Farzad Mohammadi
Street address
Farabi hospital, Qazvin square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical science, Farabi Eye Research Center
Full name of responsible person
Dr Ali Sadeghi-tari
Street address
Farabi Hospital,quazvin square
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical science, Farabi Eye Research Center
Proportion provided by this source
100
Public or private sector
empty

Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Eye Research Center, Farabi Eye Hospital
Full name of responsible person
S-Farzad Mohammadi
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Faculty staff/Assistant Professor
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Person responsible for updating data

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Elham Ashrafi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty