

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 1010

Email address

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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

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceTehran 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

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Eye Research Center, Farabi Eye Hospital

Full name of responsible person

S-Farzad Mohammadi

Position

Faculty staff/Assistant Professor

Other areas of specialty/work**Street address**

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Full name of responsible person

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Postal code**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