

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Short versus long term topical steroid effect on corneal haze incidence after photorefractive keratectomy with mitomycin-C

Protocol summary

Study aim

To compare the effect of short versus long term steroids on corneal haze incidence after photorefractive keratectomy with mitomycin-C

Design

Randomized clinical trial with concealed allocation, 3 parallel group and double blinded

Settings and conduct

In Noor Eye hospital, a total of 222 PRK candidates who meet the study criteria will undergo PRK surgery with MMC (0.02%) and randomly assigned to 3 groups for post-operative care (topical steroid administration). The following examinations will perform before the surgery, 1, 3, 6 and 12 months after PRK: Corneal score measurement, uncorrected and best corrected visual acuity values, refraction, cyclorefraction (before and 12 month after surgery), contrast sensitivity testing, aberrometry, IOP measurement and slit lamp examination. Refraction and IOP measurement will also be performed 2 months postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: PRK candidates (21-40 years), with refractive spherical equivalent (SE) ≤ -6 , astigmatism ≤ -2 , best corrected visual acuity (BCVA) $\geq 20/25$ and Steady refractive errors during a year before surgery
Exclusion criteria: Pregnancy, breastfeeding, using corticosteroid medications, systemic diseases, Glaucoma, any corneal irregularity or opacity and ocular surgery history

Intervention groups

Administration of topical steroid after PRK:
Betamethasone 0.1% for the first week Post-operative and after that Fluorometholone 0.1% (FML) in following order: A. FML (3 weeks) + placebo (2 months) B. FML (7 weeks) + placebo (1 month) C. FML (11 weeks)

Main outcome variables

Corneal haze score; corneal densitometry

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20180428039441N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **prospective**

Last update: **2019-01-07, 1397/10/17**

Update count: **1**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Mojgan Pakbin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8240 1675

Email address

m_pakbin@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short versus long term topical steroid effect on corneal haze incidence after photorefractive keratectomy with mitomycin-C

Public title

Steroid after PRK

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

PRK candidates in following criteria Age: 21-40 years Spherical Equivalent (SE): 0 to -6.00 Diopter Astigmatism: equal to -2.00 D or less Best corrected visual acuity (BCVA): 20/25 or better Patient's desire to participate in study and post-operative follow-ups Discontinuing soft contact lenses using 1 week and hard contact lenses 3 weeks before first examination Steady refractive errors (change < 0.5 dioptre) during a year before photorefractive keratectomy

Exclusion criteria:

Pregnancy, breastfeeding or pregnancy planning during the study period Using corticosteroid medications (topical or systemic) that interfere with the recovery process Systemic diseases such as diabetes or Thyroid disease Glaucoma or intraocular pressure greater than 21 mm Hg Keratoconus, any corneal irregularity or opacity Untreated Blepharitis or MGD (meibomian gland dysfunction) Ocular surgery history

Age

From **21 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **222**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using permuted-block randomization method. In addition to balancing the number of people between the three groups, this method It can prevent the prediction of intervention sequence. Blocks random sequence will be provided by STATA software. In order to maintenance of allocation concealment, full report will be published after completion of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of which group (intervention or placebo) they are in. Also, those who perform the tests (optometrists and the clinical ophthalmologist responsible for corneal opacity diagnosis) will also be unaware of which group (intervention or placebo) is evaluating.

Placebo

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

University Central Building, Ghods St, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417733161

Approval date

2618-07-18, 1997/04/27

Ethics committee reference number

IR.TUMS.FARABIH.REC.1397.010

Health conditions studied**1****Description of health condition studied**

Corneal haze after photorefractive keratectomy

ICD-10 code

H17.8

ICD-10 code description

Other corneal scars and opacities

Primary outcomes**1****Description**

Corneal haze score

Timepoint

Before photorefractive keratectomy, 1,2, 3, 6 and 12 months after surgery

Method of measurement

Slit lamp biomicroscopy (BD 900, Haag-Streit AG, Koeniz, Switzerland)

2**Description**

Corneal densitometry

Timepoint

Before photorefractive keratectomy, 1, 3, 6 and 12 months after surgery

Method of measurement

Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany)

Secondary outcomes**1****Description**

Myopic regression

Timepoint

Before photorefractive keratectomy, 1,3, 6 and 12 months after surgery

Method of measurement

Topcon auto-refractometer (Topcon KR 8000, Topcon Corporation Tokyo, Japan)- Trial frame- NIDEK chart projector (CPe670, 20/10–20/400; Nidek Co., Gamagori, Japan)

2**Description**

Contrast sensitivity

Timepoint

Before photorefractive keratectomy, 1, 3, 6 and 12 months after surgery

Method of measurement

CSV1000 contrast sensitivity chart (VectorVision, Dayton, OH)

3**Description**

Intraocular pressure

Timepoint

Before photorefractive keratectomy, 1,2, 3, 6 and 12 months after surgery

Method of measurement

Applanation Tonometer- Slit lamp biomicroscope (BD 900, Haag-Streit AG, Koeniz, Switzerland)

4**Description**

Corneal aberrations

Timepoint

Before photorefractive keratectomy, 1, 3, 6 and 12 months after surgery

Method of measurement

Pentacam

5**Description**

Uncorrected visual acuity

Timepoint

Before photorefractive keratectomy, 1,2, 3, 6 and 12 months after surgery

Method of measurement

NIDEK chart projector (CPe670, 20/10–20/400; Nidek Co., Gamagori, Japan)

6**Description**

Best corrected visual acuity

Timepoint

Before photorefractive keratectomy, 1,2, 3, 6 and 12 months after surgery

Method of measurement

Trial frame- NIDEK chart projector (CPe670, 20/10–20/400; Nidek Co., Gamagori, Japan)

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

1. Control group: Participants who will receive topical steroid after PRK for 3 months. A one week of Betamethasone 0.1% and 11 weeks of tapering Fluorometholone 0.1% (FML).

Category

Treatment - Drugs

2**Description**

2. Intervention group: Participants who will receive topical steroid after PRK for 2 months. A one week of Betamethasone 0.1% and 7 weeks of tapering Fluorometholone 0.1% (FML).

Category

Treatment - Drugs

3**Description**

3. Intervention group: Participants who will receive topical steroid after PRK for 1 months. A one week of Betamethasone 0.1% and 3 weeks of tapering Fluorometholone 0.1% (FML).

Category

Treatment - Drugs

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

Noor Eye Hospital

Full name of responsible person

Mojgan Pakbin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Noor Eye hospital
Full name of responsible person
Dr. Hassan Ghazizadeh 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
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Person responsible for updating data

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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

Per request, we will decide about the dissemination of the data.

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