Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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) ≥ 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)
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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
Unncorrected 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
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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
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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Mojgan Pakbin
Position
PhD student in ophthalmic research
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Master
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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