Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Loteprednol 0.5% with Fluorometholone 0.1% after Myopic Photorefractive Keratectomy (PRK)

Protocol summary

Summary

objective:To compare the efficacy and side effects of loteprednol with fluorometholone after myopic photorefractive keratectomy (PRK). the study design was non randomized, prospective, single blinded (except patients, researchers and analyzers were blinded to study), fellow eye comparison. sample size:62 Each patient was randomly allocated (according to random number table) to receive loteprednol 0.5% in one eye and fluorometholone 0.1% in another eye with the protocol of 4 times daily in the firth month, 3 times in second month and 2 times in third month. Follow-up examinations were scheduled on days 1, 3, and 5, then 1, 2 and 3 months postoperatively. Preoperative characteristics, including sex, age, manifest spherical equivalent (SE), and central corneal thickness (CCT) and postoperative outcomes, including uncorrected (UDVA) and corrected distance visual acuity (CDVA), corneal haze, intraocular pressure and drug side effects (eye redness, eye discomfort) were compared between the two groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081629386N1**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

Name

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

myself

Expected recruitment start date

2016-06-11, 1395/03/22

Expected recruitment end date

2016-08-12, 1395/05/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Loteprednol 0.5% with Fluorometholone 0.1% after Myopic Photorefractive Keratectomy (PRK)

Public title

Comparison of Loteprednol 0.5% with Fluorometholone 0.1% after Myopic Photorefractive Keratectomy (PRK)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 18 years; stable refraction for at least 12 month with myopia between -8.0 to -1.0 Diopters and astigmatism less than 4.0 Diopters; normal eye examination (except refractive error); corrected distance visual acuity (CDVA) of 20/20; no history of systemic or autoimmune disease or receiving immunosuppressive treatment; neither

pregnant nor breast feeder; using no topical ophthalmic medication; have no contraindication for PRK. Exclusion criteria: Patients were unable to return for follow-up or needed to increase drug dosage for any reason; patients who did not follow the instructions correctly; patients with anisometropia (more than 1 diopter) or significant pre-operative central corneal thickness difference between two eyes (more than 20 µm); those who received MMC just in one eye; patients with postoperative complications like keratitis.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Velenjak Ave., Yaman Ave., Arabi st., Tehran, Iran

City
tehran

Postal code

Approval date
2016-06-07, 1395/03/18

Ethics committee reference number
IR.SBMU.MSP.REC.1395.101

Health conditions studied

1

Description of health condition studied
intraocular pressure

ICD-10 code
H40.6

ICD-10 code description
Glaucoma secondary to drugs

Primary outcomes

1

Description
intraocular pressure post photorefractive keratectomy

Timepoint
pre operation and 1,2,3 month post op

Method of measurement
Intraocular pressure was measured over central cornea by Goldmann applanation tonometer

Secondary outcomes

1

Description
visual acuity

Timepoint
pre operative and 1,2,3 month post operatively

Method of measurement
Snellen chart

2

Description
corneal haze

Timepoint
3 month post operatively

Method of measurement
slit lamp examination

3

Description
ocular surface side effects related to topical drugs including eye redness and eye discomfort

Timepoint
3 month post operatively

Method of measurement
question

Intervention groups

1

Description
control group: Another eye of each patient was received Flourometholone 0.1% four times a day for the first month, then three times a day for the second month and two times a day for the third month post operatively.

Category
Treatment - Drugs

2

Description
intervention group: Each patient was randomly allocated

to receive loteprednol 0.5% in one eye four times a day for the first month, then three times a day for the second month and two times a day for the third month post operatively.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Torfeh Eye Hospital
Full name of responsible person
Hossein Mohammad Rabie
Street address
Sepah Sq., Baharestan st., Tehran, Iran
City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Velenjak, Yaman Ave., Arabi st.
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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
Vice Chancellor Of Research, Shahid Beheshti University of Medical Sciences
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
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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