Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effect of betamethasone vs. Lotemax vs. Floucort in post PRK IOP

Protocol summary

Study aim
Comparison of the effect of Betamethasone vs. Lotemax vs. Floucort in post PRK IOP; measuring the effect of IOP on residual myopia; effect of Myopia on different refractive groups; the time needed to have normal IOP after cessation of drop

Design
Parallel group, single blind, randomised controlled trial

Settings and conduct
Simple randomization; optometrists and examiners and data analyzer are blind to the type of drop.

Participants/Inclusion and exclusion criteria
Patients referring to Farabi eye hospital refractive surgery clinic; myopia less than 6 and PRK candidate

Intervention groups
PRK candidates will be randomely devided into 3 groups. Each group get either betamethasone floucort or lotemax. The IOP will be checked after one month.

Main outcome variables
UDVA; CDVA; Sphere; Cylinder; IOP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190207042650N1**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**
Update count: **0**

Registration date
2019-03-03, 1397/12/12

Registrant information

Name
Hesam Hashemian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4473 7065

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h_hashemian@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of betamethasone vs. Lotemax vs. Floucort in post PRK IOP

Public title
Comparison of different steroids in post PRK IOP

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Myopia<6 PRK candidate

Exclusion criteria:
Unwilling to accept the concept.

Age
From **20 years** old

Gender
Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Optometrists and examiners and data analysor are blind to the type of drop.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Institutional Research Ethics Committee Farabi Eye Hospital,Tehran University of Medical Sciences
Street address
Farabi Eye Hospital, Qhazvin sq.
City
Tehran
Province
Tehran
Postal code
133661616351
Approval date
2018-05-12, 1397/02/22
Ethics committee reference number
IR.TUMS.FARABIH.REC.1397 .004

Health conditions studied

1

Description of health condition studied
PRK candidate
ICD-10 code
H40.6
ICD-10 code description
Glaucoma secondary to drugs

Primary outcomes

1

Description
IOP
Timepoint
IOP measurement after 1 and 3 month
Method of measurement
Goldman Tonometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Eyedrop Bethametasone (0.1% sinadaru) every 6 hours for one month
Category
Treatment - Drugs

2

Description
Intervention group: Eyedrop Floucort (0.1%suspension Sinadaru) every 6 hours for one month
Category
Treatment - Drugs

3

Description
Intervention group: Eyedrop Lotemax (loteprednol etabonate ophthalmic suspension) 0.5% (Bausch & Lomb) every 6 hours for one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Eye Hospital
Full name of responsible person
Dr Hosein Sadrolsadat
Street address
Farabi Eye Hospital, Ghazvin Sq.
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+98 21 5540 0003
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h-hashemian@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammadali Sahraeian
Street address
Ghods st., Keshavarz blvd.
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Postal code
1417653761
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+98 21 8898 7381
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msahrai@sina.tums.ac.ir
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 Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hesam Hashemian
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available