Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Clinical efficacy of Fluorometholone versus Loteprednol eye drops after photorefractive keratectomy: A triple-blinded randomized clinical trial

Protocol summary

Study aim

To compare the anti-inflammatory efficacy and safety of Fluorometholone 0.1% versus Loteprednol 0.5% following photorefractive keratectomy.

Design

This study is a simple randomized and triple-blinded controlled trial (phase 3) with parallel groups that was conducted on both of eyes of 100 patients. Fluorometholone and Loteprednol were allocated to Intervention and control group.

Settings and conduct

This study was performed in Feiz hospital in Isfahan, Iran. To compare two eye drops of Fluorometholone 0.1% and Luteinprenol 0.5%, both eyes of 100 photorefractive keratectomy patients were randomized allocated for the intervention and control groups (triple blinded that all members of the research team except the clinical pharmacist were unaware of the content of the droppers).Fluorometholone and Loteprednol were allocated to Intervention and control group. The informed consent was obtained from each participant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Stable refraction error for at least 12 months; Myopia between −1.0 to −8.0 diopters; Astigmatism less than 4.0 diopters; Normal eye examination Exclusion criteria: Unwillingness to participate or continue; administration of another topical medication; need to increase the topical steroid dosage; and treatment-related complications.

Intervention groups

Intervention group was allocated to use of Fluorometholone 0.1% one drop every 6 hour for one month and control group received the Loteprednol 0.5% sterile ophthalmic suspension one drop every 6 hour for one month.

Main outcome variables

Best corrected distance visual acuity; corneal optical density.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131229015975N6**
Registration date: **2020-02-06, 1398/11/17**
Registration timing: **retrospective**

Last update: **2020-02-06, 1398/11/17**
Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

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Name of organization / entity

Semnan University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

2016-04-02, 1395/01/14

Actual recruitment end date

2016-07-31, 1395/05/10

Trial completion date

2017-04-03, 1396/01/14

Scientific title
Clinical efficacy of Fluorometholone versus Loteprednol eye drops after photorefractive keratectomy: A triple-blinded randomized clinical trial

Public title
efficacy of Fluorometholone versus Loteprednol eye drops after photorefractive keratectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Stable refraction error for at least 12 months Myopia between −8.0 to −1.0 diopters Astigmatism less than 4.0 diopters Normal eye examination
Exclusion criteria:
Unwillingness to participate or continue administration of another topical medication need to increase the topical steroid dosage treatment-related complications

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**
More than 1 sample in each individual
Number of samples in each individual: **2**
The study was conducted on both eyes of 100 patients that were randomly allocated to the intervention and control groups.
Actual sample size reached: **100**
More than 1 sample in each individual
Actual sample size in each individual: **2**
The study was conducted on both eyes of 100 patients that were randomly allocated to the intervention and control groups.

Randomization (investigator's opinion)
Randomized

Randomization description
Both eyes in each subject were randomly allocated to the Fluorometholone (FML) and Loteprednol etabonate (LE) groups using software (Saghaei random allocation software) and simple randomization. According to the random table, each eye individually assigned to one group and the other to the second group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
All patients and members of the research team who were involved the study were blinded to the contents of the eye drops. Only the clinical pharmacy technician was aware of the content of each of the eye drops.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and Technology Deputy of Isfahan University of Medical Sciences
Street address
Research and Technology Deputy of Isfahan University of Medical Sciences, Hezar Jerib Avenue, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461

Approval date
2016-05-26, 1395/03/06

Ethics committee reference number
395477

Health conditions studied

1

Description of health condition studied
Myopia correction by photorefractive keratectomy

ICD-10 code
H52.10

ICD-10 code description
Myopia, unspecified eye

2

Description of health condition studied
Astigmatism correction by photorefractive keratectomy

ICD-10 code
H52.20

ICD-10 code description
Unspecified astigmatism

Primary outcomes

1

Description
Change in best corrected distance visual acuity (BCDVA)

Timepoint
Before intervention and on days one, three, and five and then at months one and three postoperatively.

Method of measurement
Eye examination, slit-lamp biomicroscopy and fundus examination assessment

2

Description
Corneal optical density
Timepoint
Before intervention and on days one, three, and five and then at months one and three postoperatively.
Method of measurement
Corneal densitometry was performed with a rotating camera cornea tomography system (Pentacam®).

Secondary outcomes

1

Description
Intraocular pressure
Timepoint
Before intervention and on days one, three, and five and then at months one and three postoperatively.
Method of measurement
Goldman applanation tonometry (GAT)

2

Description
Side effects
Timepoint
On days one, three, and five and then at months one and three postoperatively.
Method of measurement
Clinical assessment

Intervention groups

1

Description
Intervention group: One eye in each subject was randomly allocated to use of 0.1% Fluorometholone eye drops packaged in droppers (Floucort®, SinaDarou Co., Tehran, Iran) that was prescribed one drop every 6 h for one month.
Category
Treatment - Drugs

2

Description
Control group: The another eye in each subject was randomly allocated to use of the 0.5% Loteprednol sterile ophthalmic suspension packaged in identical droppers (Lotemax®, Bausch & Lomb Inc., Rochester, NY, USA) that was prescribed one drop every 6 hour for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz hospital
Full name of responsible person
Ali Salehi
Street address
Feiz hospital, Modarres Ave., Isfahan, Iran.
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mohsen Pourazizi

Position
Resident

Latest degree
Medical doctor

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)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Primary outcome data can be shared.

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
Descriptive analysis is allowed on requested data

From where data/document is obtainable
Mohsen Pourazizi, Department of Ophthalmology, Isfahan University of Medical Sciences, Isfahan, Iran Email: m.pourazizi@yahoo.com

What processes are involved for a request to access data/document
The request is discussed in the Center Committee and after approval, the data is submitted to the applicant over a period of approximately one month.

Comments