

# 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

Mohsen Pourazizi

##### Name of organization / entity

Semnan University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 1445 1385

##### Email address

m.pourazizi@sem-ums.ac.ir

##### 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

Isfahan

##### 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.

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8165647194

#### **Phone**

+98 31 3445 2031

#### **Email**

salhi109@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Dr. Shaghayegh Haghjoo Javanmard

#### **Street address**

Research and Technology Deputy of Medical Sciences, Hezar Jerib Avenue, Isfahan

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research@mui.ac.ir

### **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

**Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hasan Razmjoo

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammad Mikaniki

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Ophthalmology

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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**