# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

# Comparative study of two artificial tear drops, hyaluronic acid containing artificial tears versus hyaluronic free artificial tears in controlling post surgical eye discomfort following photorefractive keratectomy .

## Protocol summary


**Summary**

The purpose of this study is to compare the benefits of the hyaluronic acid containing eye drops with those without hyaluronic acid in reducing ocular discomfort, accelerating reepithelialization and improving vision after surgery. This is a single-center, triple-blind, randomized clinical study with control without placebo. Candidates for refractive surgery willing to participate in our trial will be enrolled in the study after signing the informed consent. Participants will be divided randomly into three groups by block random sampling. Inclusion criteria are basically the criteria for refractive surgery. Exclusion criteria are any corneal or main systemic disease. Based on previous studies (α=0.05, power=80%) estimated sample size is n=118. All three groups will receive bandage contact lenses, diclofenac, betamethasone and chloramphenicol after surgery. Group 1 will receive preservative free artificial tears (Artelac) and group 2 will have hyaluronic acid containing artificial tears (Artelac advance). The control group receives no artificial tears. We will scratch the labels on each tear drop container before handing it over to the patients, in order to keep them blind about the drug they are using. On the first and the fourth day after surgery, we will ask the participants to fill in a questionnaire. The questionnaire contains questions about the onset of pain, time of maximal pain and the severity of eye discomfort ranked from zero to ten. The main components of eye discomfort include pain, epiphora, foreign body sensation, blurred vision and photophobia. On third or fourth day after surgery, reepithelialization and on lens removal day, corneal epithelial defect will be checked. One, three and six months after surgery, visual acuity and corneal haze will be checked. We will also perform aberrometry six months after surgery. The examiner and the analyzer will both be masked. We expect less pain and ocular discomfort, faster visual recovery and fewer complications in those treated with hyaluronic acid containing artificial tear drops.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013060713567N2**
Registration date: **2013-10-03, 1392/07/11**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2013-10-03, 1392/07/11

**Registrant information**


**Name**

Mehrdad Mohammadpour

**Name of organization / entity**

Tehran university of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 5542 6286

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**Recruitment status**

**Recruitment complete**


**Funding source**

Eye Research Center, Farabi hospital, Vice-chancellor for research Tehran University of Medical Sciences


**Expected recruitment start date**

2013-10-23, 1392/08/01

**Expected recruitment end date**

2014-03-23, 1393/01/03

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparative study of two artificial tear drops, hyaluronic acid containing artificial tears versus hyaluronic free artificial tears in controlling post surgical eye discomfort following photorefractive keratectomy .

**Public title**
Comparing different artificial tear drops on post operative ocular discomfort after photorefractive keratectomy.
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
Inclusion criteria: Over 18 year of age, Less than 0.5 Diopter change in visual acuity in the previous year, Myopia -1.0 to -6.0, Astigmatism 0.75 to 3.0, Hyperopia +1.0to +4.0, Corneal stroma more than 450 micron, Pupil size less than 6mm. Exclusion criteria: Keratoconus, Herpetic keratitis, Corneal dystrophy, Corneal degeneration, Cataract, Glaucoma, Dry eye, Lag ophthalmos, Uveitis, Blepharitis, diabetes, Pregnancy, Breast feeding, Auto immune disease, Immunodeficiency, History of keloid formation.
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **118**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committee at Tehran university of medical science
**Street address**
Qods Ave., Keshavarz Ave., Enghelab Ave., Tehran
**City**
Tehran
**Postal code**
**Approval date**
2012-06-10, 1391/03/21
**Ethics committee reference number**
92-01-43-19812

## Health conditions studied

### 1

**Description of health condition studied**
hyperopia, myopia
**ICD-10 code**
H54.3
**ICD-10 code description**
mild or no visual impairment, binocular

## Primary outcomes

### 1

**Description**
Ocular discomfort (including pain, epiphora, foreign body sensation, blurred vision and photophobia)
**Timepoint**
First and fourth day post operation
**Method of measurement**
Questionnaire

### 2

**Description**
Visual acuity
**Timepoint**
On the first, third and sixth month after surgery
**Method of measurement**
Snelen chart

### 3

**Description**
Aberrometry
**Timepoint**
Sixth months after surgery
**Method of measurement**
Aberrometer

### 4

**Description**
Corneal haze
**Timepoint**
On the first, third and sixth month after surgery
**Method of measurement**
Slit lamp

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

For first experimental group, Mitomycin C is used prior to operation, contact lens bandages are used right after surgery and three different eye drops are administered for the following week: Chloramphenicol 0.1% every six hours for four days. Betamethasone 0.1% every six hours for two weeks and then tapered over two weeks. Diclofenac 0.1% every six hours for a day. Additionally for all patients fluorometholone 0.1% is started on the second month, administered every six hours and then tapered off over two months. For this group Artelac advanced is used as the artificial tear. This is a hyaluronic acid containing artificial tear used every four hours for the first week and then tapered off over three months.

**Category**

Treatment - Drugs

### 2

**Description**

For the second experimental group, Mitomycin C is used prior to operation, contact lens bandages are used right after surgery and three different eye drops are administered for the following week: Chloramphenicol 0.1% every six hours for four days. Betamethasone 0.1% every six hours for two weeks and then tapered over two weeks. Diclofenac 0.1% every six hours for a day. Additionally for all patients fluorometholone 0.1% is started on the second month, administered every six hours and then tapered off over two months. This group will receive preservative free Artelac which is an artificial tear that does not contain hyaluronic acid and is used every four hours in the first week and then tapered off over three months.

**Category**

Treatment - Drugs

### 3

**Description**

For the control group, Mitomycin C is used prior to operation, contact lens bandages are used right after surgery and three different eye drops are administered for the following week: Chloramphenicol 0.1% every six hours for four days. Betamethasone 0.1% every six hours for two weeks and then tapered over two weeks. Diclofenac 0.1% every six hours for a day. Additionally for all patients fluorometholone 0.1% is started on the second month, administered every six hours and then tapered off over two months. Artificial tears are not administered to this group of patients.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Farabi hospital

**Full name of responsible person**
Dr.Mehrdad Mohammadpour

**Street address**
excimer clinic, Farabi hospital, Qazvin Sq.

**City**
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
vice-chancellor for research Tehran University of Medical Sciences

**Full name of responsible person**
Dr.Akbar Fotouhi

**Street address**
Seventh floor, Central Organization Building, Qods Ave., Keshavarz Ave., Enghelab Ave.

**City**
Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
vice-chancellor for research Tehran 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**
Tehran University of Medical Sciences

**Full name of responsible person**
Mehrdad Mohammadpour

**Position**
Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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**Other areas of specialty/work**
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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*