Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 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)

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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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Email
fatemarajabi@yahoo.com
Web page address

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