Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of contact lens removal time in inducing pain after photorefractive keratectomy in refractive surgery candidates

Protocol summary

Summary

The purpose of this study is to compare the effect of lens removal time in reducing ocular discomfort, accelerating reepithelialization and improving vision after photorefractive keratectomy. This is a single center, not blinded, randomized clinical study with control without placebo. Patients referred to Farabi Eye Hospital for refractive surgery are enrolled in our trial after signing the informed consent. The participants are then divided randomly into two groups by block random sampling. Our inclusion criteria are the general criteria for refractive surgeries and our exclusion criteria are any corneal or main systemic disease. Based on previous studies (α=0.05, power=80%) estimated sample size is n=60. For the experimental group bandage contact lens will be removed seven days after surgery and for the control group bandage contact lens will be removed after four days. In both groups chloramphenicol, betamethasone and diclofenac are administered for the following weeks. On the first day and the lens removal day, we will ask the participants to fill in a questionnaire about the eye discomfort. The questionnaire contains questions about onset of pain, time of maximal pain and the severity of eye discomfort felt in each period of time. On lens removal day, patient will be examined for corneal epithelial defect. On the first, third and sixth month after surgery, visual acuity and corneal haze will be checked. We will also perform aberrometry on the sixth month. We hypothesize better pain control, less ocular discomfort, faster visual recovery and less complication in the intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061613567N3**
Registration date: **2013-11-13, 1392/08/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2013-11-13, 1392/08/22

Registrant information

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Mehrdad Mohammadpour
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Eye Research Center, Farabi Hospital

Expected recruitment start date

2013-11-23, 1392/09/02

Expected recruitment end date

2014-02-22, 1392/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of contact lens removal time in inducing pain after photorefractive keratectomy in refractive surgery candidates

Public title

Ideal time for contact lens removal 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

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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

2013-07-27, 1392/05/05

Ethics committee reference number

92-01-43-19919-90047

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

Fourth and seventh day post operation

Method of measurement

Questionnaire

2

Description

visual acuity

Timepoint

On the first, third and sixth month after surgery

Method of measurement

snellen chart

3

Description

aberration

Timepoint

Sixth months after surgery

Method of measurement

aberrometry

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 the experimental group, bandage contact lens is removed 7th day after surgery and three different eye drops are administered for the following weeks : 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.

Category

Treatment - Other

2

Description

For the control group, bandage contact lens is used right after surgery and removed after 4 days. 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.

Category

Treatment - Other

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 science

Full name of responsible person

Dr. Masoud Younesian

Street address

Seventh floor, Central Organization Building, Qods Ave., Keshavarz Ave., Enghelab Ave. Tehran

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 science

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 science

Full name of responsible person

Mehrdad Mohammad pour

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

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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