

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Improvement of refractive outcomes in myopic regression after Laser in Situ Keratomileusis using timolol: A randomised clinical trial

Protocol summary

Summary

Our study is an unmatched and triple masked uncontrolled clinical trial in which the aim of this study is to determine the effect of Timolol in improvement of myopic regression after LASIK surgery in Basir Clinic patients. 100 eyes are included in our study and are divided in two groups. The drug used for the cases is Timolol 0.5% ophthalmic drop which is used twice a day, once every 12 hours. The placebo which is used for the control eyes is artificial tear drop which is used with the same intervals. The outcomes that are studied in this project which are measured in each follow up are visual acuity, refractive errors, pachymetry and corneal topography. The patients will drop their tears for 6 months and will be followed two times: 2 months and then 6 months after the intervention. This study includes the patients that have already performed LASIK surgery and meanwhile both of their eyes have had at least -0.5 D regression. The exclusion criteria are presence of complications during the surgery, having had background diseases such as glaucoma, heart failure, digestive problems, cancer, favism, myasthenia gravis, or asthma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706271258N1**

Registration date: **2009-12-05, 1388/09/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-12-05, 1388/09/14

Registrant information

Name

Mohammad Mansouri

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2205 6391

Email address

mmansouri@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Basir Eye Clinic, Tehran University of Medical Sciences

Expected recruitment start date

2009-04-07, 1388/01/18

Expected recruitment end date

2009-11-09, 1388/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improvement of refractive outcomes in myopic regression after Laser in Situ Keratomileusis using timolol: A randomised clinical trial

Public title

Improvement of refractive outcomes in myopic regression after Laser in Situ Keratomileusis using timolol: A randomised clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having undergone Lasik surgery, both eyes have had at least -0.5 D return Exclusion criteria: Incidence of complications during the surgery, presence

of background diseases such as glaucoma, heart failure, digestive problems, cancer, favism, myasthenia gravis, or asthma

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran Univesity of Medical Sciences

Street address

6th floor, main building of Tehran Univesity of Medical Sciences, Keshavarz blvd and Ghods Ave. cross.

City

Tehran

Postal code**Approval date**

2009-03-04, 1387/12/14

Ethics committee reference number

7581610387

Health conditions studied**1****Description of health condition studied**

Regression after lasik surgery

ICD-10 code

H52.1

ICD-10 code description

Myopia

Primary outcomes**1****Description**

Refractive error

Timepoint

before intervention; 2 months and 6 months after intervention

Method of measurement

auto refractive, objective refractive, subjective refractive

Secondary outcomes

empty

Intervention groups**1****Description**

Timolol drop; every 12 hours for each eye; for 6 months

Category

Treatment - Drugs

2**Description**

Artificial tear drop; every 12 hours for each eye; for 6 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Basir Eye Clinic

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Science

Full name of responsible person

Karimi

Street address

Tehran University of Medical Science building, Keshavarz boulevard

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Science

Proportion provided by this source**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

2**Sponsor****Name of organization / entity**

Basir Eye Clinic

Full name of responsible person

Dr. Shojaei

Street address

Basir Eye Clinic, Jamalzade street, Azadi Avenue

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Basir Eye Clinic

Proportion provided by this source**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

Mohmmmd Mansouri

Position

student

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Baghiatallah Hospital

Full name of responsible person

Ahmad Shojaei

Position

Ophthalmologist

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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

