

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of using mitomycin-c during Laser Assisted Sub-Epithelial Keratectomy on the corneal endothelium: A Clinical Trial.

Protocol summary

Summary

The purpose of this study is to evaluate the effect of Mytomycin-C on the Corneal Endothelium during Excimer Laser Surface Ablation. This clinical trial was unicenter, prospective, interventional, masked study, conducted at Basir eye center, Tehran, Iran. Bilateral myopic patients scheduled to have surface ablation procedure were recruited. The inclusion criteria was ablation depths less than 65 μm . Patients with unstable refraction, suspicious of keratoconus, excessive dry eyes, impaired wound healing processes, lenticular changes, corneal dystrophy, history of ocular surgery, anterior or posterior uveitis, glaucoma, retinal diseases, and also ablation depths of 65 μm or more were excluded. Sample size is 100 patients. One eye was randomly assigned to receive intraoperative topical MMC, and Balanced Salt Solution (BSS) was used in the fellow eye of the same patient. The outcome measure of the study is endothelial cell density 3 and 6 months post surgical.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110087741N1**

Registration date: **2012-01-08, 1390/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-08, 1390/10/18

Registrant information

Name

Mina Almasi

Name of organization / entity

Tehran university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Basir Eye Center

Expected recruitment start date

2010-11-06, 1389/08/15

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of using mitomycin-c during Laser Assisted Sub-Epithelial Keratectomy on the corneal endothelium: A Clinical Trial.

Public title

Effect of Mytomycin-C on the Corneal Endothelium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Myopic patients with ablation depths less than 65 μm . Exclusion criteria: Patients with unstable refraction, suspicion of keratoconus, excessive dry eyes, impaired wound healing processes, lenticular changes, corneal dystrophy, history of ocular surgery, anterior or posterior uveitis, glaucoma, and retinal diseases.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **100****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**

Tehran university of medical sciences

Street address

Pursina avenue, Keshavarz Boulevard

City

Tehran

Postal code**Approval date**

2008-08-25, 1387/06/04

Ethics committee reference number

87-04-61-7585

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

myopia

ICD-10 code

H53, H54

ICD-10 code description

Visual disturbances and blindness

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

Endothelial cell density

Timepoint

pre surgical and 3 and 6 months post surgical

Method of measurement

specular microscopy

Secondary outcomes

empty

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

One eye was randomly assigned to receive intraoperative topical MMC, and Balanced Salt Solution (BSS) was used in control group. In each subject, MMC 0.02% (0.2 mg/ml) solution was applied on the ablated zone of the selected eye. The 7 mm round cellulose sponge soaked in MMC was kept in the target area for 5 seconds. Then the sponge was picked up and residual MMC was thoroughly irrigated with BSS.

Category

Treatment - Drugs

2**Description**

In control group BSS was applied on the ablated zone.

Category

Treatment - Drugs

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

Basir eye center

Full name of responsible person

Dr Ramezan zade

Street address

North Jamalzade

City

Tehran

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

Basir eye center

Full name of responsible person

Dr Ahmad Shojaee

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Number 359, alley Sheibani, before Fatemi Avenue,
North Jamalzade street, 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
Basir eye center
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

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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