Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 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

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Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

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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 size
Target 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
Street address
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

Contact
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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