Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Intraoperative Mitomycin C Versus Bevacizumab-methycelluse-mixture in Combined Phacoemulsification and Non Penetrating Deep Sclerectomy on Intraocular pressure in patients suffering from open angle glaucoma

Protocol summary

Summary

The aim of this study is to compare the effect of Mitomycin C with Bevacizumab-Methycelluse compound in phacoemulsification and non-penetrating deep sclerectomy combined surgery on ocular pressure of the patients with open-angle glaucoma. This is a controlled, randomized, double blinded, controlled with other drug, and single-centered clinical trial. The whole patients, with diagnosis of open-angle glaucoma, admitting to the Glaucoma Clinic of Charitable Eye Hospital of Tabriz University of Medical Sciences, who developed uncontrolled LOP and progressive glaucomatous injury in spite of receiving maximum anti-glaucoma medications, and have a substantial cataract concurrently will be studied. The patients who have no systemic conditions for receiving Bevacizumab, those with any kind of congenital abnormalities of anterior chamber angle, ocular infection, uveitis, previous ocular surgery, diabetes and patients less than 40 years are excluded from this study. The sample size is 30 patients, who are divided into two groups of 15. One group receive phacoemulsification and non-penetrating deep sclerectomy combined surgery together with MMC, while the other one undergo phacoemulsification and non-penetrating deep sclerectomy combined surgery together with Bevacizumab-methycelluse. The patients will be evaluated one day, three days, two weeks, four weeks, three months and six months postoperatively. The primary outcome of this study is to evaluate the reduction intra ocular pressure. The other consequences included surgical success, visual acuity, and its complications.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016122231450N2**
Registration date: **2017-01-26, 1395/11/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-26, 1395/11/07

Registrant information

Name

Ali Mostafaie

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Intraoperative Mitomycin C Versus Bevacizumab-methycelluse-mixture in Combined Phacoemulsification and Non Penetrating Deep Sclerectomy on Intraocular pressure in patients suffering from open angle glaucoma

Public title
Compare Mitomycin C with Bevacizumab-methycelluse Mixture in Cataract and Glaucoma surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The need for cataract surgery in patients with open-angle glaucoma that have glaucomatous progressive cupping and deterioration of the visual field; Diagnosis of open-angle glaucoma on maximally tolerated medical therapy with uncontrolled IOP; The need for cataract surgery in patients with open-angle glaucoma requiring multiple medications to control IOP; Patients suffering from glaucoma and cataract with impaired vision; Patients' willingness to participate in the study. Exclusion criteria: Patients with contraindications to bevacizumab such as arterial thromboembolic events, uncontrolled hypertension, and congestive heart failure,..; Discernable congenital abnormality of the anterior chamber angle; Ocular infection; Previous ocular surgery; Uveitis; Corneal diseases that could affect IOP or its measurement such as corneal opacity, large pterygium, ...; Patients who are less than 40 years; Diabetes; Neovascular glaucoma; Patient with any systemic or ocular complication.

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization was performed through block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Central building of the University, Golgasht street, Azadi street, Tabriz

City
Tabriz

Postal code
5166616471

Approval date
2016-10-10, 1395/07/19

Ethics committee reference number
IR.TBZMED.REC.1395.765

Health conditions studied

1

Description of health condition studied
Glaucoma

ICD-10 code
H40,H41,H4

ICD-10 code description
Primary open-angle glaucoma Glaucoma (primary)(residual stage): capsular with pseudoexfoliation of lens chronic simple low-tension pigmentary

Primary outcomes

1

Description
Intraocular pressure

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Goldmann applanation tonometry (mmHg)

Secondary outcomes

1

Description
Visual acuity

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Snellen charts

2

Description
Visual field

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3

months and 6 months after surgery

Method of measurement

Humphrey 24-2 SITA Standard perimetry (HFA 24-2) Or(HFA 10-2)

3

Description

Beleb morphology

Timepoint

Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement

Moorfields Bleb Grading System

4

Description

Endophthalmitis

Timepoint

Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement

Examination slitlamp

5

Description

Conjunctival necrosis

Timepoint

Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement

Examination slitlamp

6

Description

Hypertension

Timepoint

Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group 2: patients in this group will be put under general anesthesia. At first, a fornix-based conjunctival flap is created. Then, a 4x 4 mm outer parabolic flap, approximately 200 µm thick will be dissected followed by an inner concentrically 2 x 2mm scleral flap sculpted beneath the previous one. The internal flap should be dissected deep enough to have a dark reflex from the underlying choroid. The subconjunctival bevacizumab (ScB) group receive of 1.25 mg/ 0.3 ml of bevacizumab, subconjuctival injection at the end of surgery, while the cut is advanced anteriorly, Schlemm's canal is de-roofed. The two ostia of Schlemm's canal are then cannulated with the specific 190 µm cannulaand Schlemm's canal is dilated by slow and repeated injections of high-molecular-weight sodium hyaluronate . By gently pulling the inner scleral flap upwards and delicately depressing the floor of the canal and Descemet's membrane with the tip of a cotton swab, the membrane itself is then cleaved from the cornea and the cleavage is advanced in clear cornea for approximately 1 mm, thus creating the so-called 'trabeculo-descemetic window' .As soon as the window is completed, the inner scleral flap is excised. The next step is the sealing of the lake, which is obtained by tightly suturing the outer scleral flap with seven 10-0 nylon stitches. High-molecular-weight sodium hyaluronate is then injected underneath the flap to fill the intrascleral space temporarily, preventing it from collapsing and scarring in the early post-operative period. Finally, the conjunctiva is sutured in place.

Category

Treatment - Drugs

2

Description

Intervention group 1: patients in this group will be put under general anesthesia. First, a fornix-based conjunctival flap is created. Then, a 4x 4 mm outer parabolic flap, approximately 200 µm thick, will be dissected followed by an inner concentrically 2 x 2mm scleral flap sculpted beneath the previous one. The internal flap should be dissected deep enough to have a dark reflex from the underlying choroid. The MMC group received intraoperative 0.2 mg/ml MMC soaked under outer flap for 2 minutes, While the cut will advanced anteriorly, Schlemm's canal will be de-roofed. The two ostia of Schlemm's canal will be then cannulated with the specific 190 µm cannulaand Schlemm's canal is dilated by slow and repeated injections of high-molecular-weight sodium hyaluronate . By gently pulling the inner scleral flap upwards and delicately depressing the floor of the canal and Descemet's membrane with the tip of a cotton swab, the membrane itself is then cleaved from the cornea and the cleavage is advanced in clear cornea for approximately 1 mm, thus creating the so-called 'trabeculo-descemetic window'. As soon as the window is completed, the inner scleral flap is excised. The next step is the sealing of the lake, which is obtained by tightly suturing the outer scleral flap with seven 10-0 nylon stitches. High-molecular-weight sodium hyaluronate is then injected underneath the flap to fill the intrascleral space temporarily, preventing it from collapsing and scarring in the early post-operative period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Charity Eye Hospital in Tabriz

Full name of responsible person
Atena Latifi (Ophthalmology assistant)
Street address
Abasi street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tabriz University of Medical Sciences
Full name of responsible person
Atena Latifi
Street address
Central beuoilding of the university, Golgasht street, Azadi street, Tabriz
City
Tabriz
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 of Tabriz 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
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Full name of responsible person
Atena Latifi
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Ali Mostafaie
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Surgeon and Ophthalmologist, Fellowship anterior segment
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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