Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of outcomes of subtenon Mitomycin C injection Versus soaked sponges mitomycin C application in Deep Sclerectomy in patients with primery open angle glaucoma and psudoexfoliation glaucoma.

Protocol summary

Study aim
Comparison of the effectiveness of two methods of using mitomycin c in non-penetrating deep sclerectomy surgery in patients with open angle glaucoma

Design
Clinical trial, with parallel, double-blind, randomized, phase 3 groups on 40 patients and Random Allocation Software software is used for randomization of software to randomly assign to two groups of methods and Random block sampling.

Settings and conduct
Comparison of the effectiveness of using two methods of mitomycin C administration in non-penetrating deep sclerectomy surgery in patients with open angle glaucoma in Tabriz Nicookari Hospital, 40 selected patients were divided into two equal groups and in one group of soaked sponges mitomycin C application and in the other group Subthenon injection is mitomycin. In this double-blind study, outcome assessor and statistical analyzer will not know how to use the drug in surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with advanced open-angle glaucoma, drug intolerance,uncontrol intraocular pressure with maximum drug use Exclusion criteria: Patients with uveitis, patients with neovascular glaucoma, patients with corneal diseases and structural abnormalities of the anterior chamber

Intervention groups
After selecting the study groups, patients are randomly divided into two groups. In the first group, patients will be injected with subtenon 0.1 ml of 0.2 mg / ml solution of mitomycin and in the second group, patients will be exposed to a sponge soaked in mitomycin 0.2 mg / ml for 3 minutes.

Main outcome variables
Comparison of the effect of two methods of drug administration in reducing intraocular pressure; Treatment success; Bleb appearence and complications.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161218031450N5**
Registration date: **2021-08-16, 1400/05/25**
Registration timing: **retrospective**

Last update: **2021-08-16, 1400/05/25**
Update count: **0**

Registration date
2021-08-16, 1400/05/25

Registrant information

Name
Ali Mostafaie

Name of organization / entity
Tabriz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-11, 1400/04/20

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes of subtenon Mitomycin C injection Versus soaked sponges mitomycin C application in Deep Sclerectomy in patients with primery open angle glaucoma and psudoexfoliation glaucoma.

Public title

Comparison of outcomes of subtenon Mitomycin C injection Versus soaked sponges mitomycin C application in Deep Sclerectomy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with open-angle glaucoma (OAG) with advanced caping and progressive visual field defects A patient with open-angle glaucoma (OAG) who needs medication to control IOP but does not tolerate medication Patients with open-angle glaucoma (OAG) whose IOP is not well controlled despite medication. Patients with open-angle glaucoma (OAG) who need multiple medications to control IOP Willingness to participate in the study (patients with informed consent)

Exclusion criteria:

Lack of proper access to the patient for long-term follow-up Patients with any congenital abnormality of the anterior chamber angle Patients with ocular infections Patients with a history of ocular surgery Patients with uveitis Patients with corneal diseases that can affect IOP or measure it (corneal opacity, large pterygium, etc.). Patients with diabetes and hypertension Patients with neovascular glaucoma In case of any ocular or systemic complications, patients are excluded from the study

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. Blocking is usually in order Balance the number of samples assigned to each of the study groups to be used. The size of all the blocks is the same and we will have 20 blocks in this two-group experiment. Randomization tool also uses random allocation software (software allocation Random) that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients will be divided into two groups based on the randomization form. The outcome assessor will not know how the drug was used by the surgeon. The data analyzer will also be unaware of how the drug is used in both groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

University Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.TBZMED.REC.1400.269

Health conditions studied

1

Description of health condition studied

Open Angle Glaucoma

ICD-10 code

H40.1

ICD-10 code description

Open-angle glaucoma

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Before surgery (one day, 2 weeks, 1 month, 2 months, 3 months, 6 months, after surgery)

Method of measurement

Using a Goldman tonometer

Secondary outcomes

1

Description
Bleb apperance
Timepoint
2 months, 3 months, 6 months after surgery
Method of measurement
IBAG(indiana Bleb Grading Scale)

Intervention groups

1

Description
Intervention group: In this method, first subthenon injection of 0.1 ml of mitomycin C 0.2 mg / ml is performed and after conjugate massage, the flap is removed. Continuation of the surgical procedure is the same as routine non-penetrating deep sclerectomy. Mitomecin C Manufacturer KOREA UNITED PHARM. INC.
Category
Treatment - Surgery

2

Description
Control group: In this method, after removing the fornix base conj flap, a soaked sponge with mitomycin C 0.2 mg / ml is placed for 3 minutes and after washing, continue the surgical procedure as a routine non-penetrating deep sclerectomy. Mitomecin C Manufacturer KOREA UNITED PHARM. INC.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Nikoocari Hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Ali Mostafaei
Position
Associate Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available