

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

Treatment success; Bleb appearance and complications.

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;

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 primary open angle glaucoma and pseudoexfoliation 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 cupping 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

Full name of responsible person

Ali Mostafaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Mostafaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Latest degree

Subspecialist

Other areas of specialty/work

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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