

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Intracameral Bevacizumab and Trabeculectomy Versus Trabeculectomy With Mitomycin C Alone for Open Angle Glaucoma: A clinical trial

Protocol summary

Summary

The purpose of this study is to obtain the effectiveness of intracameral bevacizumab on trabeculectomy results, 51 patients with primary and pseudoexfoliative open angle glaucoma which are candidate for trabeculectomy will be divided randomly in two subgroups. In one group 1.25mg bevacizumab in 0.05 ml will be injected in anterior chamber after trabeculectomy through clear cornea incision using an insulin syringe. In the second group mitomycine 0.2 mg per ml will be applied on and under the scleral flap and under the conjunctiva for 2 minutes, followed by irrigation with 200 mL physiologic saline. At the follow up periods (1week, 1months, 3months and 6months) variables such as intraocular pressure and success rate of each method will be analyzed using proper statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042617443N1**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

Name

Mostafa Mafi

Name of organization / entity

Farabi Eye Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 9709

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Recruitment status

Recruitment complete

Funding source

Research center of Tehran University of Medical sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intracameral Bevacizumab and Trabeculectomy Versus Trabeculectomy With Mitomycin C Alone for Open Angle Glaucoma: A clinical trial

Public title

The effect of intracameral bevacizumab injection on outcome of trabeculectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primary openangle glaucoma candidate for trabeculectomy; pseudoexfoliative glaucoma candidate for trabeculectomy Exclusion criteria: age<50 ; high risk patients for cardiovascular disease

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 51

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research deputy of Tehran University of Medical Sciences

Street address

Keshavarz blv, Ghods street, 6th floor

City

Tehran

Postal code

Approval date

2013-12-05, 1392/09/14

Ethics committee reference number

92/130/2014/5

Health conditions studied

1

Description of health condition studied

primary open angle glaucoma

ICD-10 code

H40.1

ICD-10 code description

Primary open-angle glaucoma

Primary outcomes

1

Description

Intraocular pressure

Timepoint

before intervention, 1 week, 1 month, 3 month and 6 months after intervention

Method of measurement

Goldman aplanation tonometer

Secondary outcomes

1

Description

bleb morphply

Timepoint

3 and 6 months after intervention

Method of measurement

morphild grading system

Intervention groups

1

Description

trabeculectomy adjunctive with 1.25mg per 0.05 ml intracameral bevacizumab

Category

Treatment - Surgery

2

Description

trabeculectomy adjunctive with 0.2 mg mitimycine c under conjunctival and scleral flap

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi eye hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Teharn University of Medical Sciences

Full name of responsible person

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6th floor, Teharn University of Medical Sciences, Ghods street, Keshavarz Blv,

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Teharn 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

Name of organization / entity
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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