Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of success of trabeculectomy in glaucoma patients treated with trabeculectomy alone versus adjunctive intracameral bevacizumab-combined trabeculectomy: A clinical trial

Protocol summary

Summary

Objectives: to compare the success of trabeculectomy procedure with or without intracameral bevacizumab. Design: Primary open angle or pseudoexfoliative glaucoma patients 65 years or above who are candidates of trabeculectomy, will be randomized to either intervention (30 patients) or placebo (30 patients) group. Settings and conduct: Primary open angle or pseudoexfoliative glaucoma patients who are candidates of trabeculectomy by a single surgeon in Farabi Hospital, Tehran, will be randomized (using random number tables) to intervention or control groups. In the postoperative follow up visits (day 1, 7 and 14 and months 1, 3 and 6) primary and secondary outcome measures will be studied. Participants: Primary open angle or pseudoexfoliative glaucoma patients 65 years or above who are candidates of trabeculectomy (whose optic nerve function is failing on the maximum tolerated medical therapy and not likely to achieve sufficient IOP reduction with laser treatment). Exclusion criteria include patients at high risk of failure of trabeculectomy, including aphakic, pseudophakic, uveitic, neovascular and juvenile glaucoma. Intervention: in the first group, 0.05 ml (1.25 mg) bevacizumab will be injected intracamerally at the termination of trabeculectomy. In the second group 0.05 ml placebo (balanced salt solution) will be injected. Main outcome measure: success of tgrabeculectomy defined as intraocular pressure between 6 and 21 and 30% reduction compared to preoperative values.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120711647N1**

Registration date: **2013-03-20, 1391/12/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-20, 1391/12/30

Registrant information

Name

Ghasem Fakhraie

Name of organization / entity

Glaucoma Service, Farabi Eye Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-01-28, 1391/11/09

Expected recruitment end date

2013-06-30, 1392/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of success of trabeculectomy in glaucoma

patients treated with trabeculectomy alone versus adjunctive intracameral bevacizumab-combined trabeculectomy: A clinical trial

Public title
The effect of bevacizumab on success of trabeculectomy in glaucoma patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Primary open angle or pseudoexfoliative glaucoma patients 65 years or older who are candidates of standard trabeculectomy procedure (whose optic nerve function is failing or is likely to fail and is already on the maximum tolerated medical therapy and not likely to achieve a sufficient IOP reduction with laser treatment). Exclusion criteria: Patients at high risk of failure of trabeculectomy, including aphakic, pseudophakic, uveitic, neovascular and juvenile glaucoma.
Age
From **18 years** old to **99 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
The reason for this study being double-blind is: The investigator (the surgeon who performs trabeculectomies) is blinded, because at the end of operation he takes a syringe containing 0.05 ml of a clear liquid, but he does not know what is the liquid (either bevacizumab or balanced salt solution). The two mentioned liquids have similar appearance. However, a nurse who prepares the syringe with 0.05 ml liquid is told to fill it with either bevacizumab or balanced salt solution, and this information is recorded but not provided to the surgeon who performs trabeculectomies and the physician who visits the patients in the follow up period. The patient is also blinded to what he/she receives. The informed consent states that they either receive placebo or the drug bevacizumab, which is chosen by random.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Qods St., Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2013-01-13, 1391/10/24
Ethics committee reference number
91/d/130/2629

Health conditions studied

1

Description of health condition studied
Primary open-angle glaucoma
ICD-10 code
H40.1
ICD-10 code description
Glaucoma (primary)(residual stage): capsular with pseudoexfoliation of lens, chronic simple, low-tension, pigmentary

Primary outcomes

1

Description
Success of trabeculectomy
Timepoint
six months after surgery
Method of measurement
Goldmann applanation tonometry (intraocular pressure between 6 and 21 ml Hg and 30% reduction of intraocular pressure compared to preoperative values)

Secondary outcomes

1

Description
Intraocular pressure
Timepoint
Before and 1 day, 7 days, 14 days, 1 month, 3 months and 6 months following surgery
Method of measurement
Goldmann applanation tonometry

2

Description
Corrected distance visual acuity
Timepoint

Before and 1 day, 7 days, 14 days, 1 month, 3 months and 6 months following surgery

Method of measurement

clinical examination

3

Description

Morphology of filtration Bleb

Timepoint

one day, 7 days, 14 days, 1 month, 3 months and 6 months following surgery

Method of measurement

Slit lamp exam; Moorfields bleb grading system and Indiana bleb appearance grading scale

4

Description

Number of medications used to lower the intraocular pressure

Timepoint

Before and 1 day, 7 days, 14 days, 1 month, 3 months and 6 months following surgery

Method of measurement

History

5

Description

Complications of intervention including bleb leak, encapsulation and need to globe massage

Timepoint

one day, 7 days, 14 days, 1 month, 3 months and 6 months following surgery

Method of measurement

clinical examination

6

Description

Visual field

Timepoint

Before and 6 months after surgery

Method of measurement

perimetry

7

Description

Optic nerve head appearance and cup to disc ratio

Timepoint

Before and 6 months after surgery

Method of measurement

slit lamp exam and OCT of optic nerve head

8

Description

Status of nerve fiber layer

Timepoint

Before and 6 months after surgery

Method of measurement

GDX and OCT of nerve fiber layer

Intervention groups

1

Description

Intervention 1: single injection of 1.25 mg (0.05 ml; concentration 25 mg/ml) bevacizumab (monoclonal antibody against VEGF; trade name Avastin, Genentech/Roche, San Francisco, CA) in the anterior chamber at termination of trabeculectomy surgery

Category

Treatment - Drugs

2

Description

Intervention 2: single injection of placebo (0.05 ml balanced salt solution) in the anterior chamber at termination of trabeculectomy surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Ghasem Fakhraie

Street address

Qazvin Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Qods St., Keshavarz Blvd.

City

Tehran

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, Tehran 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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Full name of responsible person
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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