Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Trabeculectomy with versus without intravitreal bevacizumab in diabetic patients

Protocol summary

Summary

This is a prospective, randomized, comparitive study at Rassoul Akram Hospital, Tehran, Iran to compare the outcome of trabeculectomy with versus without intravitreal injection of bevacizumab in diabetic patients. 52 eyes from 52 diabetic patients with uncontrolled glaucoma will be enrolled. The eyes will be assigned randomly to 2 groups: the bevacizumab group will undergo trabeculectomy with adjunctive intravitreal bevacizumab and the control group will undergo trabeculectomy without intravitreal bevacizumab.The outcome measures are best-corrected visual acuity(BCVA), intraocular pressure(IOP), number of IOP lowering medications, complications, bleb morphologic features(based on the Indiana Bleb Appearance Grading Scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102219206N3**
Registration date: **2014-11-08, 1393/08/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-08, 1393/08/17

Registrant information

Name

Naveed Nilforoushan

Name of organization / entity

Eye Research Center,Rasoul Akram Hospital,Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

vice chancellor of research, Iran university of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Trabeculectomy with versus without intravitreal bevacizumab in diabetic patients

Public title

Trabeculectomy with versus without intravitreal bevacizumab in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetic patients who are candidate for trabeculectomy(inadequately controlled glaucoma with maximally tolerated medical therapy or intolerance to antiglaucoma medications). Exclusion criteria: being pregnant or currently breast feeding; past history of any ocular surgery other than cataract surgery in more than 6 months before trabeculectomy; ocular surface infection over the previous 2 weeks; systemic thromboembolic events; neovascular glaucoma; concurrent cataract surgery; age younger than 18 years old; diabetic

retinopathy which needs lasertherapy or intravitreal injection of anti- VEGF over the previous 6 months or within 6 months after trabeculectomy.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Iran University of Medical Sciences

Street address
Iran,Tehran,Iran University of Medical Sciences

City
Tehran

Postal code

Approval date
2014-10-01, 1393/07/09

Ethics committee reference number
105/3168/93/د

Health conditions studied

1

Description of health condition studied
Glaucoma

ICD-10 code
H40

ICD-10 code description
Glaucoma

Primary outcomes

1

Description
Intra Ocular Pressure

Timepoint
Days1, 7, 14, 30, 60, 90 and 180 after trabeculectomy

Method of measurement
IOP measurement by Goldmann tonometry

Secondary outcomes

1

Description
rate of qualified sugical success

Timepoint
Days 1, 7, 14, 30, 60, 90 and 180 after trabeculectomy

Method of measurement
qualified success is IOP of 21mmHg or less and at least 20% reduction in the preoperative IOP with antiglaucoma medications where the number ofthem is less than that used before surgery.

2

Description
BCVA

Timepoint
Days 1, 7, 14, 30, 60, 90 and 180 after trabeculectomy

Method of measurement
The BCVA is measured by Snellen chart.

3

Description
number of antiglaucoma medications

Timepoint
Days 1, 7, 14, 30, 60, 90 and 180 after trabeculectomy

Method of measurement
number of drugs to control the IOP

4

Description
rate of complete surgical success

Timepoint
Days 1, 7, 14, 30, 60, 90 and 180 after trabeculectomy

Method of measurement
Complete surgical success is defined by IOP of 21mmHg or less and at least20 % reduction in the preoperative pressure without any antiglaucoma medications

5

Description
bleb evaluation results

Timepoint
months 1 and 6

Method of measurement
Bleb photographs are obtained at months 1 and at the last follow-up.Bleb photographs at the last follow-up are graded by a masked glaucoma specialist(N.Ni.) who compares the study photographs with standard

photographs , according to the Indiana Bleb Appearance Grading Scale ,which is based on extension,height,vascularization, and leakage.

Intervention groups

1

Description
All surgeries are carried outby a single experienced surgeon(N.Ni.). For all eyes, after creating the scleral flap, MMC 0.02%(0.2mg/mL)isapplied using multiple thin sponges under the scleral flap between the sclera and Tenon capsule for 2 minutes. At the end of surgery, the conjunctiva is closed with10-0 nylonsutures. In the bevacizumab group after suturing the conjunctiva , 2.5mg (0.1mL)bevacizumab (Avastin) is injected intravitreally.

Category
Treatment - Drugs

2

Description
In the same fashion, trabeculectomy is performed in the control group, but without intravireal bevacizumab injection.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Rassoul Akram Hospital

Full name of responsible person
Acieh Eshaghi

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor of research,Iran University of Medical Sciences

Full name of responsible person
Mohammadi

Street address
Tehran,Iran University of Medical Sciences

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 of research,Iran 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
Eye Research Center,Rassoul Akram Hospital

Full name of responsible person
Acieh Eshaghi

Position
ophthalmology resident

Other areas of specialty/work

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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