Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Compare the effects of Avastin and Avastin combined with methylcellulose in intraocular pressure after Non-penetrating glaucoma surgery

Protocol summary

Summary

The aim of this study is to compare the effect of Avastin with Bevacizumab-Methycelluse compound in non-penetrating deep sclerectomy combined surgery on ocular pressure of the patients with open-angle glaucoma. This is a controlled, randomized, double blinded, controlled with other drug, and single-centered clinical trial. The whole patients, with diagnosis of open-angle glaucoma, admitting to the Glaucoma Clinic of Charitable Eye Hospital of Tabriz University of Medical Sciences, who developed uncontrolled LOP and progressive glaucomatous injury in spite of receiving maximum anti-glaucoma medications. The patients who have no systemic conditions for receiving Bevacizumab, those with any kind of congenital abnormalities of anterior chamber angle, ocular infection, uveitis, previous ocular surgery, diabetes and patients less than 40 years are excluded from this study. The sample size is 30 patients, who are divided into two groups of 15. One group receive non-penetrating deep sclerectomy withAvastin, while the other one undergo non-penetrating deep sclerectomy surgery with Bevacizumab-methycelluse. The patients will be evaluated one day, three days, two weeks, four weeks, three months and six months postoperatively. The primary outcome of this study is to evaluate the reduction intra ocular pressure. The other consequences included surgical success, visual acuity, and its complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121831450N1**
Registration date: **2017-04-18, 1396/01/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-04-18, 1396/01/29

Registrant information

Name
Ali Mostafaie

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 3655 1332

Email address
mostafaeia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of Avastin and Avastin combined with methylcellulose in intraocular pressure after Non-penetrating glaucoma surgery

Public title

Compare the effects of Avastin and Avastin combined with methylcellulose in intraocular pressure after Non-penetrating glaucoma surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:patients with open-angle glaucoma and uncontrolled IOP on maximally tolerated medical therapy with uncontrolled IOP Exclusion criteria:Patientswith previous glaucoma and cataract surgery,previous surgery due to trauma,angle closure glaucoma, who are less than 40 years؛ Diabetes;uveitis,Collagen vascular disease,Neovascular glaucoma,end stage glaucoma

Age
From **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

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
Office of the Vice Chancellor for Researchof Tabriz University of Medical Sciences

Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City
tabriz

Postal code

Approval date
2016-12-26, 1395/10/06

Ethics committee reference number
IR.TBZMED.REC.1935.996

Health conditions studied

1

Description of health condition studied
glaucoma

ICD-10 code
H40.1

ICD-10 code description
Primary open-angle glaucoma Glaucoma (primary)(residual stage): capsular with pseudoexfoliation of lens chronic simple low-tension pigmentary

Primary outcomes

1

Description
Intraocular pressure

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Goldmann applanation tonometry (mmHg)

Secondary outcomes

1

Description
Visual acuity

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Snellen charts

2

Description
Visual field

Timepoint
Before surgery, 6 months after surgery

Method of measurement
Humphrey 24-2 SITA Standard perimetry (HFA 24-2) Or(HF30-2)

3

Description
Beleb morphology

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Moorfields Bleb Grading System

4

Description
Endophthalmitis

Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery

Method of measurement
Examination slitlamp

5

Description
Conjunctival necrosis
Timepoint
Before surgery, 1 day, 3 days, 2 weeks, 4 weeks, 3 months and 6 months after surgery
Method of measurement
Examination slitlamp

Intervention groups

1

Description
Intervention group 1: patients in this group will be put under general anesthesia. At first, a fornix-based conjunctival flap is created. Then, a 4x 4 mm outer parabolic flap, approximately 200 µm thick will be dissected followed by an inner concentrically 2 x 2mm scleral flap sculpted beneath the previous one. The internal flap should be dissected deep enough to have a dark reflex from the underlying choroid. The subconjunctival Avastin group receive of 1.25 mg of bevacizumab, subconjuctival injection at the end of surgery, while the cut is advanced anteriorly, Schlemm's canal is de-roofed. The two ostia of Schlemm's canal are then cannulated with the specific 190 µm cannulaand Schlemm's canal is dilated by slow and repeated injections of high-molecular-weight sodium hyaluronate . By gently pulling the inner scleral flap upwards and delicately depressing the floor of the canal and Descemet's membrane with the tip of a cotton swab, the membrane itself is then cleaved from the cornea and the cleavage is advanced in clear cornea for approximately 1 mm, thus creating the so-called 'trabeculo-descemetic window' .As soon as the window is completed, the inner scleral flap is excised. The next step is the sealing of the lake, which is obtained by tightly suturing the outer scleral flap with seven 10-0 nylon stitches. High-molecular-weight sodium hyaluronate is then injected underneath the flap to fill the intrascleral space temporarily, preventing it from collapsing and scarring in the early post-operative period. Finally, the conjunctiva is sutured in place.
Category
Treatment - Drugs

2

Description
Intervention group 2: patients in this group will be put under general anesthesia. At first, a fornix-based conjunctival flap is created. Then, a 4x 4 mm outer parabolic flap, approximately 200 µm thick will be dissected followed by an inner concentrically 2 x 2mm scleral flap sculpted beneath the previous one. The internal flap should be dissected deep enough to have a dark reflex from the underlying choroid. The subconjunctival bevacizumab (ScB) group receive of 1.25 mg/ 0.3 ml of bevacizumab, subconjuctival injection at the end of surgery, while the cut is advanced anteriorly, Schlemm's canal is de-roofed. The two ostia of Schlemm's canal are then cannulated with the specific 190 µm cannulaand Schlemm's canal is dilated by slow and repeated injections of high-molecular-weight sodium hyaluronate . By gently pulling the inner scleral flap upwards and delicately depressing the floor of the canal and Descemet's membrane with the tip of a cotton swab, the membrane itself is then cleaved from the cornea and the cleavage is advanced in clear cornea for approximately 1 mm, thus creating the so-called 'trabeculo-descemetic window' .As soon as the window is completed, the inner scleral flap is excised. The next step is the sealing of the lake, which is obtained by tightly suturing the outer scleral flap with seven 10-0 nylon stitches. High-molecular-weight sodium hyaluronate is then injected underneath the flap to fill the intrascleral space temporarily, preventing it from collapsing and scarring in the early post-operative period. Finally, the conjunctiva is sutured in place.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Charity Eye Hospital in Tabriz
Full name of responsible person
neda moghaddam(Ophthalmology assistant)
Street address
Abasi street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tabriz University of Medical Sciences
Full name of responsible person
neda moghaddam
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
tabriz
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 of Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
neda moghaddam
Position
Ophthalmplogy Assistant
Other areas of specialty/work
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
tabriz
Postal code
5166616471
Phone
+98 41 3657 1670
Fax
Email
ghmoghaddam@tabrizu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Mostafaie
Position
Surgeon and Ophthalmologist, Fellowship anterior segment
Other areas of specialty/work
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
tabriz
Postal code
5166616471
Phone
+98 41 3335 5921
Fax
+98 41 3335 9680
Email
info@elibrary.tbzmed.ac.ir; dln@tbzmed.ac.ir
Web page address
www.tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
neda moghaddam
Position
Ophthalmology Aistant
Other areas of specialty/work
Street address
Central building of the university, Golgasht street, Azadi street, Tabriz
City
tabriz
Postal code
5166616471
Phone
+98 41 3657 1670
Fax
Email
ghmoghaddam@tabrizu.ac.ir
Web page address

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