Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the prophylactic effect of antiglaucoma drugs on eye pressure in patients undergoing intravitreal injection of bevacizumab

Protocol summary

Study aim
Determining the prophylactic effect of antiglaucoma drugs on eye pressure in patients undergoing intravitreal injection of bevacizumab

Design
A controlled, single-blind, randomized, phase 3 clinical trial on 108 patients. R statistical software version 4.0.2 was used for randomization

Settings and conduct
The study population in this research is all patients who are candidates for intravitreal injection of bevacizumab referred to Al-Zahra Ophthalmology Hospital. In this research, single blinding method is used. So that the person responsible for recording the results (eye resident) will not be aware of the desired intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: 1- Age more than 18 years 2- Informed and free consent to participate in the study 3- Patients who will have the first intra-boasizomat injection. Exclusion criteria also include: 1- History of retinal surgery 2- Rupture of the posterior capsule 3- High eye pressure or glaucoma 4- Use of topical medication 5- Active intraocular inflammation 6- Eye pathologies 7- Withdrawal from the study during research for any reason

Intervention groups
Patients were randomly divided into 4 groups, group A: topical timolol 0.5% (2 drops with a time interval of 10 minutes, 60-90 minutes before intervention), group B: combination of dorzolamide hydrochloride 2% and timolol maleate 0.5% and brand name Xylomol® (2 drops with an interval of 10 minutes, 60-90 minutes before the intervention), group C: oral acetazolamide 500 mg (90-120 minutes before the intervention), group D: placebo drop group (one drop artificial tears, which will be administered 2 drops with an interval of 10 minutes, 60-90 minutes before the intervention) will be divided

Main outcome variables
Intraocular pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230330057787N1**
Registration date: **2023-09-04, 1402/06/13**
Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**
Update count: **0**

Registration date
2023-09-04, 1402/06/13

Registrant information

Name
fatemeh asli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3222 9705

Email address
fateme813@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the prophylactic effect of antiglaucoma drugs on eye pressure in patients undergoing intravitreal injection of bevacizumab

Public title
effect of anti-glaucoma agents on intra ocular pressure Spikes after intravitreal bevacizumab injection in patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- Age more than 18 years 2- Informed and free consent to participate in the study 3- Patients who will have the first intra-boasizomat injection.

Exclusion criteria:
1- History of retinal surgery. 2- Rupture of the posterior capsule 3- High eye pressure or glaucoma 4- Use of topical medication (such as IOP-lowering medications and corticosteroids) 5- Active intraocular inflammation 6- Eye pathologies such as pterygium or corneal opacities that can affect the evaluation of study variables 7- Withdrawal from the study during research for any reason

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of patients to 5 groups is done by permuted stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of arrival. Then they are randomly assigned to the desired group. These permutations were created using statistical software R version 4.0.2

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, single blinding method is used. So that the person responsible for recording the results (eye resident) will not be aware of the intended intervention.

Placebo
Used

Assignment
Other

Other design features
A controlled, single-blind, randomized, phase 3 clinical trial on 108 patients. R statistical software version 4.0.2 was used for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences

Street address
Zahedan - Doctor Hasabi Square - Medical Sciences Campus

City
zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2023-03-01, 1401/12/10

Ethics committee reference number
IR.ZAUMS.REC.1401.433

Health conditions studied

1

Description of health condition studied
Eye pressure of patients undergoing intravitreal injection of bevacizumab

ICD-10 code
H40.6

ICD-10 code description
Glaucoma secondary to drugs

Primary outcomes

1

Description
Intraocular pressure

Timepoint
The beginning of the study / one minute after injection / 30 minutes after injection / 24 hours after injection

Method of measurement
At the beginning of the study, 30 minutes after the injection and 24 hours after the injection, the intraocular pressure is measured with a Goldman tonometer and one minute after the injection with Tonopen.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, 0.5% topical timolol drops (2 drops with a 10-minute interval, 60-90 minutes before the intervention) are prescribed.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, the combination of dorzolamide hydrochloride 2% and timolol maleate 0.5% with the brand Xylomol® (2 drops with a time interval of 10 minutes, 60-90 minutes before the intervention) is prescribed.

Category

Treatment - Drugs

3

Description

Intervention group: In the third group, oral acetazolamide 500 mg is administered (90-120 minutes before the intervention).

Category

Treatment - Drugs

4

Description

Control group: In this group, placebo drops (an artificial tear drop, 2 drops with a time interval of 10 minutes, 60-90 minutes before the intervention) are prescribed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Ophthalmology Hospital

Full name of responsible person
Mr. Dr. Mohammad Erish

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
Dr. Nur Mohammad Bakhshani

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Zahedan Square, Dr. Hasabi Campus, University of Medical Sciences

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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
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Mr. Dr. Mohammad Erish

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mr. Dr. Mohammad Erish

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
Associate professor

Latest degree
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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