Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative Study of the Effect of Zilomol and Timolol Drop Following Intravitreal Injection of Bevacizumab on the Improvement of Diabetic Macular Edema

Protocol summary

Study aim

- Determination and comparison of visual acuity after intravitreal injection of bevacizumab in two study groups before and after the intervention. 2-Determination and comparison of the average central thickness of the macula in the intravitreal injection of bevacizumab in the two study groups before and after the intervention. 3-Determining and comparing the average intravitreal eye pressure of bevacizumab in the two study groups before and after the intervention.

Design

A clinical trial with two intervention groups, community-based and practice-oriented, triple-blind, parallel, randomized

Settings and conduct

The population studied in the current research will be patients with diabetic macular edema who referred to Al-Zahra Ophthalmology Hospital in 1402. Sampling will be available to enter the study, and to receive the type of treatment, random sampling * The type of randomization is simple randomization. It will continue using the table of random numbers until the sample size is completed in each group. *Blinding: It is triple blind, the patient is not aware of the type of intervention performed, and on the other hand, the doctor evaluating the outcome of the study is also not aware of the type of treatment used. The statistical consultant is also not aware of the type of intervention. *Allocation concealment is done by using "sealed and waxed opaque envelopes with a random sequence".

Participants/Inclusion and exclusion criteria

The study population in the current research will be patients with diabetic macular edema who referred to Al-Zahra Ophthalmology Hospital in 1402.

Intervention groups

Zilamol drop Timolol drop

Main outcome variables

VA IOP central thickness of macula

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231126060185N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Maryam Dianat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5725

Email address

dianatmaryam60@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A Comparative Study of the Effect of Zilomol and Timolol Drop Following Intravitreal Injection of Bevacizumab on the Improvement of Diabetic Macular Edema

Public title
The Effect of Zilomol and Timolol Drop on the Diabetic Macular Edema

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People with bilateral diabetic macular edema (central retinal thickness more than 300 microns) with center-involved and thickness difference less than 25% between 2 eyes who have not undergone any eye interventions (such as eye surgery, intraocular injection) eye, eye lasers and eye treatment and eye local treatment) are not included.
Exclusion criteria:
Patients during pregnancy and breastfeeding Active intraocular inflammation treated with topical corticosteroids Eye pathologies such as pterygium or corneal opacities that can affect the evaluation of study variables A patient with high eye pressure who is treated with intraocular pressure lowering drugs and corticosteroids History of allergy to CAIs and sulfonamide drugs Patients who use systemic antihypertensive drugs such as acetazolamide or beta blockers

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **34**
More than 1 sample in each individual
Number of samples in each individual: **2**
RIGHT AND LEFT EYE

Randomization (investigator's opinion)
Randomized

Randomization description
For each patient, one of the eyes is randomly selected to receive dorzolamide-timolol drops (Zimolol) and the opposite eye receives timolol drops at a dose of one drop every 8 hours. The label of the drops is removed in order to make their shape uniform and the drops are coded with random three-digit numbers (391 and 538) (code 391: dorzolamide-timolol drops/code 538: timolol drops). The person injecting is unaware of which eye the patient is using dorzolamide-timolol and which timolol. At the end, the statistics expert will be presented with the information related to BCVA, CMT and IOP of both eyes in coded form (code 391 and 538).

Blinding (investigator's opinion)
Triple blinded

Blinding description
It is blinded in three ways, the patient is not aware of the type of intervention performed, and on the other hand, the doctor evaluating the outcome of the study is also not aware of the type of treatment used. The statistical consultant is also not aware of the type of intervention. Opaque sealed with random sequence is done. In this way, the random sequence is determined first, then the sequences are recorded on a card and the cards are placed inside the envelopes in order. On the outer surface of the envelopes. The numbering is done and it is placed in the box in order. The participants choose an envelope in the order of arrival and the intervention group is determined.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of zahedan university of medical Sciences

Street address
Motahhary Street

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
98167 37789

Approval date
2023-10-17, 1402/07/25

Ethics committee reference number
IR.ZAUMS.REC.1402.315

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy is one of the most important causes of blindness in the world, and due to the fact that it affects people of working age, it has tremendous socio-economic consequences in societies. (1) The prevalence of DME in diabetic patients in Iran is estimated to be around 30%. (DME, Diabetic Macular Edema) can be defined as macular thickening and cystoid edema, which can cause diabetic retinopathy mostly with exudate deposition.

ICD-10 code

E08.321

ICD-10 code description

Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema

Primary outcomes

1

Description

Central thickness of macula

Timepoint

Before intervention-1month -2month-3month post IVB and drop

Method of measurement

- measurement using macular OCT imaging

2

Description

IOP

Timepoint

Before intervention-1month -2month-3month post IVB and drop

Method of measurement

measurement by Goldman tonometer

Secondary outcomes

1

Description

Visual acuity

Timepoint

Before intervention and one ,two,three month post

Method of measurement

LogMar

Intervention groups

1

Description

Intervention group 1: the eye receiving xylomol drops. One day before the intravitreal injection of bevacizumab, drops are placed every 8 hours in the eye that will be injected, and after the injection, they continue every 8 hours for one month and thus To be injected three times and to use intravitreous drops for one month after injection. And after each month of injection, visual acuity, intraocular pressure and central thickness of the macula are measured

Category

N/A

2

Description

Intervention group: the second eye, recipient of timolol drops, is performed in the same way as the first intervention group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Maryam Diant

Street address

Motahhary street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167 37789

Email

Dianatmaryam89@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

Street address

Motahhary Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167 37789

Phone

+98 919 346 7860

Email

Dianatmaryam89@gmail.com

Grant name

Vice President of Research and Research of Zahedan University of Medical Sciences

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

Maryam Dianat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Motahhary

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167 37789

Phone

+98 54 3329 5725

Fax

Email

dianatmaryam60@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Dianat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Motahhary

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167 37789

Phone

+98 54 3329 5725

Fax

Email

dianatmaryam60@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Dianat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Motahhary

City

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Province

Sistan-va-Balouchestan

Postal code

98167 37789

Phone

+98 54 3329 5725

Fax

Email

dianatmaryam60@gmail.com

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