

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### A Comparative Study of the Effect of Zilamol 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**

Motahary 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 xyломol 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 intravitreal 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  
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## Person responsible for updating data

### Contact

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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