

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effect of dorzolamide drop with intravitreal avastin injection in decreasing central macular thickness in diabetic patient with diabetic macular edema

#### Protocol summary

##### Study aim

Effect of dorzolamide drop with intravitreal avastin injection in decreasing central macular thickness in diabetic patient with diabetic macular edema that refer to Isfahan Feiz eye center 2017-18

##### Design

Clinical trials with control group, with parallel and randomized groups and double blind

##### Settings and conduct

Patients were collected in Feyz Hospital in Isfahan in an accessible manner. The left or right eyes of the patients were randomly assigned to the intervention group using a lottery envelope. Before and after treatment, the amount of visual activity was measured and according to Macular Cochran eye imaging, Foya thickness and macular volume. Patient and researcher did not know the contents of the therapeutic package used in the operating room.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Diabetic patients with retinopathy who have macular edema. A transparent mediator for a thorough examination Visual activity of both eyes are better than 1/10 and less than or equal to 4/10 Patient consent. The thickness of the central area of the macula at the start of treatment is greater than 300 microns  
Exclusion Criteria: History of bone surgery The presence of atrophy, oscillas, fibrosis and hard exudates in the macular center that affects vision. Uncontrolled blood pressure, myopia of more than 8 diopters, active eye infectious disease, other complications of diabetes in the eyes and synchronous eye pathologies.

##### Intervention groups

Intravascular injection of Avastin was performed for all eyes at the start of treatment and 1 month later. In the intervention group, drops were given to the topical drops and in the control group, artificial tear drops were dropped every 12 hours and continued for 2 months.

#### Main outcome variables

Sight strength, Foie thickness, Macular volume

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131229015975N5**

Registration date: **2019-09-05, 1398/06/14**

Registration timing: **retrospective**

Last update: **2019-09-05, 1398/06/14**

Update count: **0**

##### Registration date

2019-09-05, 1398/06/14

##### Registrant information

##### Name

Mohsen Pourazizi

##### Name of organization / entity

Semnan University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 1445 1385

##### Email address

m.pourazizi@sem-ums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

2017-09-23, 1396/07/01

**Actual recruitment end date**

2018-03-21, 1397/01/01

**Trial completion date**

2018-09-23, 1397/07/01

**Scientific title**

Effect of dorzolamide drop with intravitreal avastin injection in decreasing central macular thickness in diabetic patient with diabetic macular edema

**Public title**

Effect of dorzolamide drop with intravitreal avastin injection in decreasing central macular thickness

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diabetic patients with retinopathy who have macular edema due to increased macular thickness or vision loss are indicative of anti-VEGF treatment. A transparent mediator for a thorough examination Visual activity of both eyes are better than 1/10 and less than 4/10 Patient consent to Participate in the Study The thickness of the central area of the macula at the start of treatment is greater than 300 microns

**Exclusion criteria:**

History of bone surgery The presence of atrophy, scarring, fibrosis and hard exudates in the macular center that affects visual acuity. Uncontrolled blood pressure Presence of active eye infectious disease There are other complications of diabetes in the eyes, which leads to an increase in the thickness of the macula. The presence of other synchronous eye pathologies such as glaucoma and cataracts.

**Age**

From **18 years** old to **62 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **16**

Actual sample size reached: **16**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were selected in a non-probable manner, but the patients' eyes were randomly assigned to two groups of intervention and control based on the lottery.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Each eye was randomly assigned to receive one group of the medication. All preparations were individually prepared for each patient and patients and investigators were kept blinded to the randomized allocation and details of series of the medications throughout the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2017-09-22, 1396/06/31

**Ethics committee reference number**

IR.MUI.IRC.1396.3.651

**Health conditions studied****1****Description of health condition studied**

Edema macula

**ICD-10 code**

H58.8

**ICD-10 code description**

Other specified disorders of eye and adnexa in diseases classified elsewhere

**Primary outcomes****1****Description**

visual activity

**Timepoint**

Before and two months after the intervention.

**Method of measurement**

Examination by ophthalmologist

**2****Description**

Foie thickness

**Timepoint**

Before and two months after the intervention.

**Method of measurement**

Optical Coherence Topography and Examination by

ophthalmologist

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#### **Description**

Macular volume

#### **Timepoint**

Before and two months after the intervention.

#### **Method of measurement**

Optical Coherence Topography and Examination by ophthalmologist

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: 16 diabetic patients with elevated double-walled macular thickness in one eye randomly selected in addition to intravascular injection of Avastin at baseline and 1 month later, Dorzolamide topical drops were dropped every 1 to 12 hours and continued for 2 months. Found.

#### **Category**

Treatment - Other

#### 2

#### **Description**

Control group: 16 diabetic patients with bilateral double-blind macular thickness in one eye randomly selected, in addition to intravascular injection of avastin at the start of treatment, and 1 month later, artificial tear drop was dropped every 1 to 12 hours and continued for 2 months.

#### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Feyz Hospital in Isfahan

##### **Full name of responsible person**

Farhad Fazel

##### **Street address**

Quds Square.

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### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Ziba faraj Zadegan

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Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue.

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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**

Esfahan 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**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohsen Pourazizi

##### **Position**

Ophthalmologist Resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Ophthalmology

##### **Street address**

Feiz Hospital

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Isfahan

##### **Province**

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##### **Postal code**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All information is unpublished after being denied and two years after the publication of the article.

### When the data will become available and for how long

two years after the publication of the article

### To whom data/document is available

Medical students and professors and specialized assistants of the ophthalmology group.

### Under which criteria data/document could be used

To compare existing information with similar results at another time or other implementation.

### From where data/document is obtainable

Send a request for cooperation to fazel43@yahoo.com and get permission from the Research Vice-Dept of Isfahan University of Medical Sciences.

### What processes are involved for a request to access data/document

Send a request for cooperation to fazel43@yahoo.com and get permission from the Research Vice-Dept of Isfahan University of Medical Sciences.

### Comments