

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the changes in the OCT angiography after the Intra Vitreal Injection of Bevacizumab in diabetic Patients with Clinically Significant Macular Edema.

#### Protocol summary

##### Study aim

To determine changing in the OCT angiography after the Intravitreal injection of Bevacizumab in diabetic patients with clinically significant macular edema

##### Design

The trial of one group without control group, without blinding , with a sample size of 35 patients with diabetic macular edema

##### Settings and conduct

In this study, complete ophthalmology examination and OCTA are provided for 35 eyes of patients with clinically significant macular edema, Before and 1 month after intra vitreal injection of Bevacizumab (or stivant) . OCTA geometrical findings of FAZ area and thicknes are analyzed .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with Diabetic macular edema.  
Exclusion criteria: Myopia more than 6 diopters; history of vitrectomy;macular hole ,CNV, Hydroxychloroquine consumption.

##### Intervention groups

Intervention group: Patients with diabetic macular edema. These patients will receive 1.25 mg of Bevacizumab (or Stivant ), intravitreally by other specialist.

##### Main outcome variables

Change in macular thickness; change in FAZ area

#### General information

##### Reason for update

completion and correction of exclusion criteria and correction of some sentences that needs correction

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190518043622N1**  
Registration date: **2020-09-04, 1399/06/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-15, 1399/08/25**

Update count: **1**

##### Registration date

2020-09-04, 1399/06/14

##### Registrant information

###### Name

Arash ghazanfari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3633 3615

###### Email address

arash.ghazanfari@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-04, 1397/03/14

##### Expected recruitment end date

2021-07-10, 1400/04/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the changes in the OCT angiography after the Intra Vitreal Injection of Bevacizumab in diabetic Patients with Clinically Significant Macular Edema.

##### Public title

Evaluation of Bevacizumab effect on diabetic macular

edema in diabetic patients .

IR.SUMS.MED.REC.1397.079

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with diabetic macular edema age between 30-75 years old Central macular thickness more than 300 microne based on OCT measurement

### Exclusion criteria:

Myopia more than 6 diopters other macular diseases like macular hole and CNV Some drugs :Hydroxycloquine consumption Previous history of chemotherapy and radiotherapy History of vitrectomy

## Age

From **30 years** old to **75 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **35**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

In this study, we assessed features of OCT Angiography images to find vascular and morphological changes before and after the injection of Bevacizumab.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Floor 7, Central building of Shiraz University of Medical Sciences, Zand street, Shiraz

##### City

Shiraz

##### Province

Fars

##### Postal code

۷۱۳۳۶ - ۷۱۳۴۸

#### Approval date

2018-05-21, 1397/02/31

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Diabetic macular edema

#### ICD-10 code

H36.0

#### ICD-10 code description

Diabetic retinopathy

## Primary outcomes

### 1

#### Description

Change in macular thickness

#### Timepoint

Before intervention and 1 month after intervention

#### Method of measurement

Evaluation of macular thickness with OCT angiography

### 2

#### Description

Change in geometrical feature of FAZ area

#### Timepoint

Before intervention and 1 month after intervention

#### Method of measurement

Evaluation of geometrical features of macula with OCT angiography and analyzing it with MATLAB

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intravitreal injection of 1.25 mg of Bevacizumab(or stivant) will be performed by other expert in operation room under sterile condition ( for patients with diabetic macular edema). The patients will be followed before and one month after operation. In this study we did not intervene and we analyzed the OCTA images before and after what other experts injected to evaluate macular changes.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Postchi Ophthalmology Center

##### Full name of responsible person

Mohammad Hosein Norooz zade

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Ophthalmology Clinic of Poostchi , Zand Boulevard,  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

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Floor 7, Central bulding of Shiraz University of Medical  
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Vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Arash Ghazanfari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

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Unit 1, Baran building (No 169), Takestan avenue,  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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Resident of ophtalmology

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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