

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

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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

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

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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

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Full name of responsible person

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Sponsors / Funding sources

1

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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

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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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