

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Determining the association of response rate to Intravitreal injection of bevacizumab and macular vessel density in patients with diabetic macular edema using optical coherence tomography angiography (OCT-A) in outpatients referred to Feyz Hospital

Protocol summary

Study aim

Determining the association of response rate to Intravitreal injection of bevacizumab and macular vessel density in patients with diabetic macular edema using optical coherence tomography angiography (OCT-A)

Design

First, their information was recorded, then OCT-A is taken from both eyes in 3 * 3 mm slabs (to eliminate Projection Artifact, the slabs have been changed from 6 * 6 to 3 * 3 mm) and the amount Vascular density in the superficial and deep layers in the Superior And Inferior Hemifeild in the macular and paraphute regions is determined. 3-4 mm apart from the limbus is done by intravitreal injection and these injections are continued up to three times a month. Finally, one month after the last injection, OCT-A was taken again.

Settings and conduct

The aim of this study was to evaluate the response to internal vitreous injection of vascular endothelium growth factor inhibitors based on vascular density in outpatient diabetic patients referred to Feyz Hospital with non-proliferative retinopathy with diabetic macular edema with inclusion criteria from which OCT is obtained.

Participants/Inclusion and exclusion criteria

The present study is a longitudinal study with a pre-post design. Samples are selected based on inclusion criteria and OCT is taken from them. Women with a central macular thickness (CMT) above 305 µm and men a CMT above 320 µm were included in the study.

Intervention groups

Samples have non-proliferative diabetic retinopathy with diabetic macular edema that were included in the study based on inclusion criteria.

Main outcome variables

the vascular density in the superficial and deep layers

was examined and compared before and after the injection. a 10% reduction in CMT was considered to be an appropriate level of response to treatment. The used imaging system in our study was RTVue XR Avanti (Optovue Inc., Fremont, CA, USA).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220416054548N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Mahya ghazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

ghazyzeynab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the association of response rate to Intravitreal injection of bevacizumab and macular vessel density in patients with diabetic macular edema using optical coherence tomography angiography (OCT-A) in outpatients referred to Feyz Hospital

Public title

Determining the association of response rate to Intravitreal injection of bevacizumab and macular vessel density in patients with diabetic macular edema using optical coherence tomography angiography (OCT-A)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Having type 1 or 2 diabetes Central macular edema based on Heidelberg's clinical examination and OCT in one or both eyes (at least 305 μ m in women and 320 μ m in men) Best modified view less than or equal to 10/7 No history of laser in the patient's eye Moderate to severe non-proliferative diabetic retinopathy with diabetic macular edema Transparent media to the extent that it does not interfere with the quality of images and their analysis (SSI: signal strength index: 37-40)

Exclusion criteria:

History of retinal vascular obstructive diseases History of intraocular injection in the last 6 months History of intraocular and retinal laser in the affected eye in the last 12 months Decreased vision following any ocular pathology other than diabetic retinopathy High Myopia (≥ -8) History of eye surgery in the last 6 months Uncontrolled glaucoma (IOP ≥ 30 mmHg despite maximal treatment) Uncontrolled diabetes Uncontrolled blood pressure (SBP ≥ 180 mmHg or DBP ≥ 100 mmHg) Connective tissue diseases

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

Central Headquarters, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St.

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2021-12-10, 1400/09/19

Ethics committee reference number

IR.MUI.MED.REC.1400.682

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

Determining the association of response rate to Intravitreal injection of bevacizumab and macular vessel density in patients with diabetic macular edema using optical coherence tomography angiography (OCT-A) in outpatients referred to Feyz Hospital

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**

Blood sugar levels

Timepoint

Before the intervention

Method of measurement

blood test

2

Description

blood pressure

Timepoint

Before the intervention

Method of measurement

Physical examination

3

Description

Severity of retinopathy

Timepoint

Before the intervention

Method of measurement

Examination with slit lamp

4

Description

The best modified vision

Timepoint

Before the intervention

Method of measurement

Physical examination

5

Description

Eye pressure

Timepoint

Before the intervention

Method of measurement

Measurement with tonometer

6

Description

The central thickness of the macula

Timepoint

Before the intervention and 1 month after the last injection

Method of measurement

OCT

7

Description

FAZ level

Timepoint

Before the intervention and 1 month after the last injection

Method of measurement

OCT-A

8

Description

Vascular density of the surface layer

Timepoint

Before the intervention and 1 month after the last injection

Method of measurement

OCT-A

9

Description

Deep layer vascular density

Timepoint

Before the intervention and 1 month after the last injection

Method of measurement

OCT-A

10

Description

Total vascular density

Timepoint

Before the intervention and 1 month after the last injection

Method of measurement

OCT-A

Secondary outcomes

1

Description

The central thickness of the macula

Timepoint

One month after the last injection

Method of measurement

OCT

2

Description

FAZ level

Timepoint

One month after the last injection

Method of measurement

OCT-A

3

Description

Vascular density of the surface layer

Timepoint

One month after the last injection

Method of measurement

OCT-A

4

Description

Deep layer vascular density

Timepoint

One month after the last injection

Method of measurement

OCT-A

5

Description

Total vascular density
Timepoint
One month after the last injection
Method of measurement
OCT-A

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Intervention groups

1

Description

Intervention group: The present study is a longitudinal study with a pre-post design. Samples are selected sequentially from outpatients to ophthalmology clinics who have non-proliferative diabetic retinopathy with diabetic macular edema based on inclusion criteria and OCT is taken from them. Women with a central macular thickness (CMT) above 305 µm and men a CMT above 320 µm were included in the study. First, comprehensive examinations were performed on the patients and their information was recorded. After that OCT-A images was taken from both eyes of the patients in 3 × 3 mm slabs (to remove projection artifacts, the slabs were changed 6 × 6 mm to 3 × 3 mm). The level of vascular density was determined in the superficial and deep layers and superior and inferior hemifield defects were determined in the macular and parachute areas. After that, the patients who were candidates for treatment based on the standard protocols of diabetic macular edema (DME) treatment, in a sterile organized environment, 1.25 mg of bevacizumbe was injected intravenously with a distance of 3–4 mm from the limbus. For any of patients, the injections were continued up to three times every month. Finally, one month after the last injection, OCT-A scan was taken again and the vascular density in the superficial and deep layers was examined and compared before and after the injection. In this study, a 10% reduction in CMT was considered to be an appropriate level of response to treatment. The used imaging system in our study was RTVue XR Avanti (Optovue Inc., Fremont, CA, USA).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Feyz Educational Therapeutic Center
Full name of responsible person
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Feyz Educational and Medical Center, at the beginning of Modares St., Ghods Square.
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73461-81746

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mansour Siavash Dastjerdi
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Vice Chancellor for Research and Technology,
Building No. 4, Isfahan University of Medical Sciences
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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
Mahya Ghazi
Position
Ophthalmology resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Latest degree

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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