Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 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)

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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 µm in women and 320 µm 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
Isfehan
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

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

Mahya Qazi

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Feyz Educational and Medical Center, at the beginning of Modares St., Ghods Square.

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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 and Health Services, Hezar Jerib St.

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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

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