

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Combined anti-Vascular Endothelial Growth Factor (VEGF) and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment of diabetic macular edema: A Randomized clinical trial

Protocol summary

Study aim

Structural and functional difference between two groups of case and control in order to achieve better treatment regarding minor side effects to treat macular edema secondary to DM.

Design

A clinical trial of two groups of diabetic macular edema patients with parallel double-blind groups will be performed on 64 randomized eyes by simple method.

Settings and conduct

The study was conducted at the Institute of Ophthalmology in Shiraz to compare the injection of intravitreal bevacizumab alone and bevacizumab with triamcinolone in two groups of patients with diabetic macular edema.

Participants/Inclusion and exclusion criteria

inclusion criteria: Participants Patients with center-involved macular edema due to DM, baseline BCVA between 20/40 and 20/40, and a CSFT of more than 320 microns on Heidelberg Spectralis SD-OCT machine. Eyes with previous treatment were allowed to be enrolled if they had intravitreal anti-VEGF or corticosteroids for at least two and four months before The exclusion criteria comprised monocular patients, presence of any ocular neovascularization or ONH shunts, pathologic myopia, glaucoma, any significant media opacity or concomitant retinal disorder (such as aging macular degeneration, retinal vein occlusion, vitreomacular traction, epiretinal membrane, etc.), previous intraocular surgery (other than uneventful cataract surgery), and noncompliance with any of the therapeutic or diagnostic interventions

Intervention groups

Two treatments are compared to bevacizumab alone and bevacizumab plus triamcinolone for the treatment of diabetic macular edema. Group 1 will receive Intravitreal bevacizumab and Group 2 will receive Intravitreal bevacizumab and Triamcinolone injections.

Main outcome variables

best corrected visual acuity Intraocular pressure Cataract formation central subfield foveal thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201120049450N6**

Registration date: **2025-04-20, 1404/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2025-04-20, 1404/01/31**

Update count: **0**

Registration date

2025-04-20, 1404/01/31

Registrant information

Name

Ehsan Namvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 4088

Email address

namvar_e@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-05, 1404/01/16

Expected recruitment end date

2025-07-06, 1404/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined anti-Vascular Endothelial Growth Factor (VEGF) and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment of diabetic macular edema: A Randomized clinical trial

Public title

Combined anti-Vascular Endothelial Growth Factor (VEGF) and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment of diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with center-involved macular edema due to DM, baseline BCVA between 20/40 and 20/50, CSFT of more than 320 microns on Heidelberg Spectralis SD-OCT machine. Eyes with previous treatment were allowed to be enrolled if they had intravitreal anti-VEGF or corticosteroids for at least two and four months before

Exclusion criteria:

monocular patients, presence of any ocular neovascularization or ONH shunts, pathologic myopia, glaucoma, any significant media opacity or concomitant retinal disorder (such as aging macular degeneration, retinal vein occlusion, vitreomacular traction, epiretinal membrane, etc.), previous intraocular surgery (other than uneventful cataract surgery), noncompliance with any of the therapeutic or diagnostic interventions

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

We use simple randomization using table of random numbers. The treatment group of each patient will be determined after passing the registration criteria. Randomization will be performed by an assistant who had no role in treating the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

this study will be double blinded. participants, principle investigator, healthcare providers who care for participants during the trial, data collectors, outcome

assessors before and after treatment will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

ethics committee at Shiraz university of Medical Sciences

Street address

Khalili street

City

Shiraz

Province

Fars

Postal code

7193616641

Approval date

2025-03-11, 1403/12/21

Ethics committee reference number

IR.SUMS.REC.1403.571

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

retinal disorder

ICD-10 code

other reti

ICD-10 code description

H35

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

BCVA (best corrected visual acuity)

Timepoint

one month after injection

Method of measurement

According to refractive errors acuted by auto spectacle with correcting lenses examined to achieve best corrected vision by snellen chart

2**Description**

IOP(Intraocular pressure)

Timepoint

one day and one month after injection

Method of measurement

Tonometry is the method of measurement which is performed by many different method in our study it is constructed by airpuff

3

Description

Cataract formation

Timepoint

one month after injection

Method of measurement

LOCS II grading system

4

Description

CSFT(central subfield foveal thickness)

Timepoint

one month after injection

Method of measurement

Macular optical coherence tomography macular volume demographic thickness map

Secondary outcomes

empty

Intervention groups

1

Description

Control group: intravitreal injection of bevacizumab

Category

Treatment - Surgery

2

Description

Intervention group: intravitreal injection of bevacizumab and triamcinolone

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

shiraz university of medical science

Full name of responsible person

Ehsan namvar

Street address

khalili hospital, khalili street, shiraz, fars, iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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namvar.e@gmail.com

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

Ehsan namvar

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Combined anti-VEGF and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment of diabetic macular edema :A Randomized clinical trial

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

references or meta-analysis

From where data/document is obtainable

namvar.e@gmail.com

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

email to responsible person

Comments