Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 inorder 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 ۲۰/۴۰۰ and ۲۰/۴۰, and a CSFT of more than ۳۲۰ 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
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Iran (Islamic Republic of)
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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 ۲۰/۴۰۰ and ۲۰/۴۰, CSFT of more than ۳۲۰ 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 acuited 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
Tonometery 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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Sponsors / Funding sources

1

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Email
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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
Ehsan namvar
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
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Person responsible for updating data

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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