Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

: Combined anti-VEGF and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment ofmacular edema due to central retinal vein occlusion: A Randomized clinical trial

Protocol summary

Study aim
Comparison of combined anti-VEGF and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment of macular edema due to central retinal vein occlusion

Design
A clinical trial of two groups of patients with macular edema due to CRVO 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 macular edema due to CRVO.

Participants/Inclusion and exclusion criteria
inclusion criteria: Participants Patients with center-involved macular edema due to CRVO, 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, diabetic retinopathy, 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 macular edema due to CRVO. 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: **IRCT20201120049450N7**
Registration date: **2026-07-13, 1405/04/22**
Registration timing: **retrospective**

Last update: **2026-07-13, 1405/04/22**
Update count: **0**

Registration date
2026-07-13, 1405/04/22

Registrant information

Name
Ehsan Namvar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3627 4088

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-05, 1405/01/16

Expected recruitment end date
2026-07-06, 1405/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
: Combined anti-VEGF and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment ofmacular edema due to central retinal vein occlusion: A Randomized clinical trial

Public title
: Combined anti-VEGF and low-dose triamcinolone intravitreal injections versus anti-VEGF alone for treatment ofmacular edema due to central retinal vein occlusion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants Patients with center-involved macular edema due to CRVO baseline BCVA between ۲۰/۴۰۰ and ۲۰/۴۰ CSFT of more than ۳۲۰ microns on Heidelberg Spectralis SD-OCT machine 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:
comprised monocular patients presence of any ocular neovascularization or ONH shunts pathologic myopia glaucoma any significant media opacity concomitant retinal disorder (such as aging macular degeneration, diabetic retinopathy, 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
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
"Patients who meet all eligibility and registration criteria will be randomized to the treatment groups using simple randomization based on a table of random numbers, with an allocation ratio of 1:1. Randomization will be performed only after a participant has been confirmed as eligible and enrolled in the study. To minimize selection and allocation bias, the randomization sequence will be implemented by an assistant who is not involved in patient recruitment, clinical management, treatment administration, or outcome assessment. The treating investigators will not participate in the allocation process. This procedure is intended to ensure that group assignment remains unbiased and independent of clinical decision-making."
Blinding (investigator's opinion)
Double blinded
Blinding description
"This study will employ a double-blind design. Blinding will extend to all individuals involved in the trial to minimize potential biases that could arise from knowledge of treatment allocation. Specifically: Participants: Will be unaware of which treatment arm they have been assigned to. The Principal Investigator: Will be blinded to the treatment assignments throughout the study duration. Healthcare Providers: All healthcare professionals directly involved in the care of participants during the trial, including those administering treatments or managing participant well-being, will be blinded. Data Collectors: Individuals responsible for collecting data at any point during the trial will be unaware of the participants' treatment allocation. Outcome Assessors: Personnel responsible for assessing participant outcomes, both before and after the intervention period, will be blinded to treatment assignments."
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
2025-12-10, 1404/09/19
Ethics committee reference number
IR.SUMS.REC.1404.484

Health conditions studied

1

Description of health condition studied
retinal disorders

ICD-10 code
H35
ICD-10 code description
Other retinal disorders

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
Intervention group: intravitreal injection of combined bevacizumab and triamcinolone. Participants in this group will receive intravitreal injections of both an anti-vascular endothelial growth factor (anti-VEGF) agent and a low-dose corticosteroid (Triamcinolone Acetonide).
Category
Treatment - Surgery

2

Description
Control group: intravitreal injection of bevacizumab. Participants in this group will receive intravitreal injections of an anti-VEGF agent alone.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
shiraz university of medical science
Full name of responsible person
Ehsan Namvar
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khalili hospital, khalili street, shiraz, fars, iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammadhosein Nowroozzadeh
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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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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 macular edema due to central retinal vein occlusion: 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