Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the effect of intravitreal injection of Bevacizumab (Stevenet) alone with intravitreal injection of Bevacizumab and Triamcinolone in the treatment of diabetic macular edema with a thickness greater than 500 microns in patients referred to Shafa Hospital.

Protocol summary

Study aim

Determination and comparison of macular thickness changes in IVB and IVB/IVT injections Determining and comparing changes in visual acuity in IVB and IVB/IVT injections

Design

Clinical trialClinical trial with two intervention groups, double-blind, randomized with STATA software

Settings and conduct

Eye examinations including BCVA, Goldman tonometry, indirect dilation ophthalmoscopy, lens opacity grading, diabetic retinopathy grading based on ETDRS will be performed. Group I, 0.05 mL (1.25 mg) bevacizumab injection 3 doses per month. In the second intervention group, 0.025 mL (1 mg) of laboratory triamcinolone acetone will be added to the first IVB injection with an aspartate syringe. Patients will be examined on days 1 and 7 after the operation in terms of anterior chamber reaction and intraocular pressure measurement. Ophthalmological examination and OCT will be done again in 4, 8 and 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with clinically significant DME based on ETDRS criteria and central thickness greater than 500 microns. Exit criteria History of previous DME treatment (focal or panretinal laser coagulation or IVB or IVT), eye surgery, glaucoma or ocular hypertension, monocular vision, pregnancy, Significant media opacity, CMT<500, The patient's absence in follow-up in the following weeks

Intervention groups

In the first intervention group, 0.05 ml (1.25 mg) of bevacizumab will be randomly injected invitro 3 times a month. In the second intervention group, 0.025 ml (1 mg) of in vitro triamcinoloneacetone will be added to the first IVB injection with a separate syringe.

Main outcome variables

The primary outcome will be change in BCVA based on logMAR at week 12 relative to baseline,the secondary outcome will include a change in CMT at weeks 4, 8,12.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211130053229N1**
Registration date: **2023-03-05, 1401/12/14**
Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**
Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

maysam shekofteh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3212 4727

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15
Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravitreal injection of Bevacizumab (Stevenet) alone with intravitreal injection of Bevacizumab and Triamcinolone in the treatment of diabetic macular edema with a thickness greater than 500 microns in patients referred to Shafa Hospital.

Public title
Comparison of the effect of intravitreal injection of bevacizumab (Stevenet) alone with intravitreal injection of bevacizumab and triamcinolone in the treatment of diabetic macular edema with a thickness greater than 500 microns in patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with clinically significant DME according to ETDRS criteria Patients with clinically significant DME based on criteria of central thickness greater than 500 microns
Exclusion criteria:
History of previous DME treatment (focal or panretinal laser coagulation or IVB or IVT) Eye surgery Glaucoma or ocular hypertension monocular vision pregnancy Significant media opacity CMT<500 The patient's absence in follow-up in the following weeks
Age
No age limit
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of eyes will be done by block randomization method and with the help of STATA software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the surgeon will not know the type of injected drug and the drug will be drawn by the operating room personnel.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
The beginning of Haft Bagh Alavi Blvd, University of Medical Sciences Campus
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2020-04-23, 1399/02/04
Ethics committee reference number
IR.KMU.AH.REC.1399.004

Health conditions studied

1

Description of health condition studied
Diabetic macular edema
ICD-10 code
E08.311
ICD-10 code description
Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema

Primary outcomes

1

Description
BCVA change based on LogMAR chart
Timepoint
BCVA measurement at baseline and at week 12
Method of measurement
Based on Snellen chart

Secondary outcomes

1

Description
Changes in central macular thickness (CMT)

Timepoint
CMT changes at weeks 4, 8, 12
Method of measurement
Optical coherence tomography

Intervention groups

1

Description
Intervention group: In the first intervention group, bevacizumab 0.05 ml (1.25 mg) 3 doses will be randomly injected monthly (Avastin; Genen-tech, Inc., South San Francisco, CA (made for F. Hoffmann) -La Roche, Ltd., Basel, Switzerland)-off label drug), in both groups, the injection is done in one eye (the eye with a macular thickness of more than 500 microns). All injections will be performed by a surgeon. The injection is performed after local anesthesia with the help of a 29-gauge needle. Randomization of the eyes is done by the block randomization method and with the help of STATA software. The patient and the surgeon are not aware of the type of injected drug and the drug will be drawn by the prestel in the operating room. (double blinded) All patients will be examined on the 1st and 7th day after the procedure for interior chamber reaction and intraocular pressure measurement. Full ophthalmological examination and OCT will be done again in 4, 8 and 12 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: In the second intervention group, intravitreal triamcinolone acetonide 0.025 ml (1 mg) ((Holzkirchen, Germany) - off label drug) will be added to the first IVB injection with a separate syringe. In both groups, the injection is done in one eye (the eye with macular thickness above 500 microns). All injections will be performed by a surgeon. The injection is performed after local anesthesia with the help of a 29-gauge needle. Randomization of the eyes is done by the block randomization method and with the help of STATA software. The patient and the surgeon are not aware of the type of injected drug and the drug will be drawn by the prestel in the operating room. (double blinded) All patients will be examined on the 1st and 7th day after the procedure for interior chamber reaction and intraocular pressure measurement. Full ophthalmological examination and OCT will be done again in 4, 8 and 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Hospital
Full name of responsible person
Maysam Shkofteh
Street address
East Kosar Boulevard, Kosar Square, Kerman
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7618751151
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Arash Danesh Talab
Street address
The beginning of Haft Bagh Alavi Boulevard, University of Medical Sciences campus
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international@kmu.ac.ir
Grant name
Kerman University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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

Kerman University of Medical Sciences

Full name of responsible person
Kerman University of Medical Sciences

Position
Assiasant

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Ophthalmology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Resident

Latest degree
Medical doctor

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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The data obtained in the study can be shared after making the participants unrecognizable.

When the data will become available and for how long
After publishing the results, it will be possible to access the data.

To whom data/document is available
The data will be available to medical researchers.

Under which criteria data/document could be used
The use of data is unrestricted if it is not subject to plagiarism.

From where data/document is obtainable
researchers can ask Dr. Meysam Shokfteh to receive the data.

What processes are involved for a request to access data/document
The esteemed applicant must inform the above mentioned researcher of his / her details andthe reason for the need for the data. After consulting with other researchers, He will announce hisagreement or disagreement.

Comments