

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 trial Clinical 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)

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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

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East Kosar Boulevard, Kosar Square, Kerman

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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

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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
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Other areas of specialty/work
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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

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 and the reason for the need for the data. After consulting with other researchers, He will announce his agreement or disagreement.

Comments