

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of Intravitreal bevacizumab and intravitreal dexamethasone with intravitreal bevacizumab in the treatment of diabetic macular edema

Protocol summary

Study aim

Assessment and comparison of the efficacy of intravitreal bevacizumab and intravitreal dexamethasone co-therapy with intravitreal bevacizumab monotherapy in the treatment of patients with persistent diabetic macular edema

Design

Non-randomized, superiority, two-arm parallel trial

Settings and conduct

Torfeh Medical Center (a tertiary referral eye center)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) patients with type 2 diabetes mellitus, 2) at least 18 years of age, 3) BCVA>20/400, 4) persistent DME: patients who had received at least 3 intravitreal injections of Bevacizumab given at monthly intervals but still had a CMT >300 microns caused by intraretinal or subretinal fluid as well as a reduction of <10% of baseline CMT based on spectral-domain OCT (SD-OCT) measured 1 month after at least 3 intravitreal bevacizumab injections Exclusion criteria: Panretinal photocoagulation (PRP), any intraocular surgery, or intravitreal steroids within the temporal vicinity of the study period; previous Pars Plana vitrectomy; intraocular pressure (IOP)>21, diagnosed glaucoma, or history of a steroid-induced rise in IO; concomitant retinal disorder causing macular edema; present vitreous hemorrhage, media opacities, ocular inflammation; myopia $\geq$ 6D; and poor quality OCT images.

Intervention groups

Group 1: three monthly intravitreal injections of bevacizumab (1.25 mg) Group 2: three monthly intravitreal injections of bevacizumab (1.25 mg) + intravitreal dexamethasone (200 micrograms)

Main outcome variables

1- Best-corrected visual acuity 2- Central macular thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220328054362N1**

Registration date: **2022-08-22, 1401/05/31**

Registration timing: **retrospective**

Last update: **2022-08-22, 1401/05/31**

Update count: **0**

Registration date

2022-08-22, 1401/05/31

Registrant information

Name

Hosein Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 5952

Email address

hosein.nouri.2018@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

2019-02-04, 1397/11/15

Actual recruitment end date

2021-08-11, 1400/05/20

Trial completion date

2021-12-21, 1400/09/30

Scientific title

Comparison of the effectiveness of Intravitreal bevacizumab and intravitreal dexamethasone with intravitreal bevacizumab in the treatment of diabetic macular edema

Public title

Intravitreal bevacizumab alone or in combination with intravitreal dexamethasone for the treatment of diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with type 2 diabetes mellitus at least 18 years of age best-corrected visual acuity >20/400 persistent DME - i.e., patients who had received at least 3 intravitreal injections of Bevacizumab given at monthly intervals but still had a CMT >300 microns caused by intraretinal or subretinal fluid as well as a reduction of <10% of baseline CMT based on spectral domain OCT (SD-OCT) measured 1 month after at least 3 intravitreal bevacizumab injections Time from the last intravitreal injection more than 1 month and less than 2 months

Exclusion criteria:

Patients who had undergone laser photocoagulation (PRP) during the last 3 months or needed PRP until the end of the study patients who had received intravitreal steroids within the last 6 months Patients who had undergone any intraocular surgery during the last 3 months Patients with previous Pars Plana vitrectomy Patients with intraocular pressure (IOP)>21 or known cases of primary or secondary glaucoma or history of steroid responding Patients with other concomitant retinal disorders that could give rise to macular edema Patients with vitreous hemorrhage, media opacities, ocular inflammation myopia $\geq$ 6D those with poor quality OCT images

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **54**

More than 1 sample in each individual

Number of samples in each individual: **2**

Individuals' eyes were the samples in this study; from each individual one or both eyes were recruited, subject to the eye(s) fulfilling the recruitment criteria

Actual sample size reached: **81**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Individuals' eyes were the samples in this study; from each individual one or both eyes were recruited, subject to the eye(s) fulfilling the recruitment criteria.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Science

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7th Floor, Bldg No. 2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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Province

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Postal code

1983963113

Approval date

2022-03-15, 1400/12/24

Ethics committee reference number

IR.SBMU.MSP.REC.1400.840

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**

Best-corrected visual acuity (Logarithm of the Minimum Angle of Resolution)

Timepoint

before intervention and 1 month after the last injection

Method of measurement

Snellen chart

2**Description**

Central macular thickness
Timepoint
before intervention and 1 month after the last injection
Method of measurement
Spectral-domain optical coherence tomography (SD-OCT;
6 × 6 mm images taken with the macular cube protocol
on the Heidelberg SD-OCT)

Secondary outcomes

1

Description
Incidence of intraocular pressure rise (adverse event)
Timepoint
1 month after the last injection
Method of measurement
Goldmann applanation tonometry

2

Description
Incidence of other adverse events (endophthalmitis,
uveitis, vitreous hemorrhage, rupture, and retinal
detachment)
Timepoint
throughout the intervention and one-month follow-up
periods
Method of measurement
Reported by participants - Relevant diagnostic workup
upon presentation of symptoms in participants' eyes

Intervention groups

1

Description
Routine intervention group: Three consecutive monthly
intravitreal injection of 1.25 mg bevacizumab
(Avastin®100mg/4ml Vial, Roche Pharma, Switzerland)
Category
Treatment - Drugs

2

Description
Additive intervention group: three consecutive monthly
intravitreal co-injections of 1.25 mg bevacizumab
(Avastin®100mg/4ml Vial, Roche Pharma, Switzerland)
and 200 µg of intravitreal dexamethasone (Dexon®
8mg/2ml Amp, Sinadarou, Iran)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Torfeh Hospital
Full name of responsible person

Saeed Karimi
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Ibn-Sina St, District 12
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Karimi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available