Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 ≥ 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) + intravireal 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)

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+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 bevacizimab 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 ≥ 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

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

City
Tehran

Province
Tehran

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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
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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