

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of intravitreal bevacizumab (Avastin®) plus vitamin D supplementation on diabetic macular edema in vitamin D deficient patients

Protocol summary

Study aim

1. Determination of the effect of intravitreal injection of bevacizumab (Avastin) along with correction of vitamin D deficiency on central macular thickness in patients with diabetic macular edema and vitamin D deficiency; 2. Determination of the effect of intravitreal injection of bevacizumab (Avastin) with correction of vitamin D deficiency on corrected distance visual acuity (CDVA) in patients with diabetic macular edema and vitamin D deficiency; 3. Determining the relationship between vitamin D levels and the severity of macular edema

Design

Clinical trial with parallel and randomized groups & control group

Settings and conduct

The study will be performed in the retinal clinic of Labbafinejad Hospital in Tehran. Both groups receive 3 baseline IVB as a base, and oral vitamin D supplement is prescribed for correction of deficiency in group 2 by 50000 units/week for eight weeks. No blinding is designed.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Patients with type 2 diabetes mellitus and diabetic macular edema (DME) with greater central macular thickness of equal to and greater than 300 microns and corrected distance visual acuity of more than 0.1 LogMAR; Main exclusion criteria: Severe Vitamin D Deficiency (Less than 10 ng / ml), Taking vitamins Supplements upon entry

Intervention groups

Group 1 = Control Group = Deficient / Insufficient without Supplementation= with vitamin D deficiency and diabetic macular edema receiving IVB only; Group 2 = Deficient / Insufficient with Supplementation: With vitamin D deficiency and diabetic macular edema which will receive IVB and oral vitamin D supplementation (intervention)

Main outcome variables

Corrected distance visual acuity, central macular thickness, vitamin D level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046978N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Sepehr Roozdar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

roozdars@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-04, 1399/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravitreal bevacizumab (Avastin®) plus vitamin D supplementation on diabetic macular edema in vitamin D deficient patients

Public title

Evaluation of vitamin D effect on diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diabetes mellitus type 2 and diabetic macular edema Central macular thickness equal and greater than 300 micron Corrected distance visual acuity of greater than 0.1 LogMAR

Exclusion criteria:

History of any intraocular surgery (except uncomplicated cataract surgery which at least 6 months are passed) History of intravitreal injection of bevacizumab, other anti-VEGFs and steroid within 3 past months Epiretinal membrane or vitreomacular traction History of retinal vascular accidents History of uveitis Pregnant or breastfeeding women Using vitamin supplementation Not taking vitamin D supplementation based on the study protocol during follow up period Patients with severe vitamin D deficiency (<10 ng/ml) Macular disease and consequent visual impairment due to causes other than diabetic macular edema Hypercalcemia and hyperphosphatemia Serum creatinin > 3 mg/dl

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple and individual randomization using tables of random numbers

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 Sciences

Street address

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

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Postal code

1983963113

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.SBMU.MSP.REC.1397.553

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**

Change in central macular thickness in microns

Timepoint

Before treatment, 1 month, 3 months and 6 months after third baseline IVB

Method of measurement

Optical coherence tomography device

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Patients with insufficient/ deficient levels of vitamin D and diabetic macular edema; Intervention: IVB

Category

Treatment - Drugs

2

Description

Intervention group: Patients with insufficient/deficient levels of vitamin D and diabetic macular edema;
Intervention: IVB+Vitamin D oral supplementation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad Hospital

Full name of responsible person

Sepehr Roozdar

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Paydarfard st, 9th Boostan, Pasdaran Ave.

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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?

No

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

Sepehr Roozdar

Position

Resident of Ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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

Not applicable

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

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

Data Dictionary

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