# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluation of the effect of Interferon Alfa-2b in combination with intra-vitreal injection of Bevacizumab in the treatment of diabetic macular edema: a randomized double-blinded clinical trial

## Protocol summary

**Study aim**

Evaluation of the effect of Interferon Alfa-2b in combination with intra-vitreal injection of Bevacizumab in the treatment of diabetic macular edema: a randomized double-blinded clinical trial

**Design**

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 49 patients.

**Settings and conduct**

In this study, diabetic patients referred to the retina clinic of Torfeh Hospital in Tehran, are examined within the specified time interval .Only one eye from each patient is included in the study. For both groups, 3 intravitreal injections of bevacizumab with a dose of 1.25 mg will be performed at one-month intervals. In the first group, interferon 2b α drops (1 MU/Ml) start immediately after the first injection, and patients use one drop every 6 hours in the affected eye for three months. In the second group, placebo (artificial tears) is prescribed for patients.

**Participants/Inclusion and exclusion criteria**

Diabetic patients over 18 years old; Macular edema involving the center; BCVA between 20/400-40/20; The central thickness of the macula is greater than or equal to 300 µm; Requires 3 IVB injections in the next 12 weeks; Retinal clarity; pupil dilation for OCT; necessary cooperation for proper fundus photography

**Intervention groups**

The control group will be treated with bevacizumab and artificial tear drops The treatment group will be treated with bevacizumab and interferon alpha 2b

**Main outcome variables**

Best corrected visual acuity (BCVA) in patients; Central macular thickness in OCT in patients; intraocular pressure in these patients;

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20230103057035N1**
Registration date: **2023-03-18, 1401/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-18, 1401/12/27**
Update count: **0**

**Registration date**

2023-03-18, 1401/12/27

**Registrant information**

**Name**

Mahdi Noori

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 3312 7993

**Email address**

drmahdinoori@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-01-21, 1401/11/01

**Expected recruitment end date**

2023-05-05, 1402/02/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Evaluation of the effect of Interferon Alfa-2b in combination with intra-vitreal injection of Bevacizumab in the treatment of diabetic macular edema: a randomized double-blinded clinical trial

**Public title**
Evaluation of the effect of Interferon Alfa-2b in diabetic macular edema

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Diabetic patients over 18 years old Macular edema involving the center. BCVA between 20/400-40/20 Central macular thickness greater than or equal to 300 µm Requires 3 IVB injections in the next 12 weeks Retinal clarity, pupillary dilation for OCT, and necessary cooperation for proper fundus photography

**Exclusion criteria:**

**Age**
From **18 years** old to **80 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **49**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Participants by covering the bottle containing medicine Clinical caregiver: keeping the condition of the patient secret before the examination Evaluator of the outcome: keeping the condition of the patient secret before the examination Data analyst: keeping the patient's condition secret until the time of analysis

**Placebo**
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**
Arabi Ave, Daneshjoo Blvd, Velenjak

**City**
Tehran

**Province**
Tehran

**Postal code**
1149847514

**Approval date**
2022-09-20, 1401/06/29

**Ethics committee reference number**
IR.SBMU.MSP.REC.1401.297

## Health conditions studied

**1**

**Description of health condition studied**
Diabetic macular edema

**ICD-10 code**
E11. 311

**ICD-10 code description**
unspecified diabetic retinopathy with macular edema

## Primary outcomes

**1**

**Description**
Decrease thickness of the central part of the macula

**Timepoint**
At the beginning of the study and one month after the third injection of bevacizumab

**Method of measurement**
Oct device (Optical coherence tomography)

## Secondary outcomes

**1**

**Description**
Improve visual acuity

**Timepoint**
Before the study and one month after the third injection of bevacizumab

**Method of measurement**
Optometry

## Intervention groups

**1**

**Description**
Control group: For this group, in sterile conditions, 3 intravitreal injections of bevacizumab with a dose of 1.25 mg will be performed at one-month intervals. In this group, patients will be prescribed placebo (artificial tears) and will be used every 6 hours for 4 months.

**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: For this group, in sterile conditions, 3 intravitreal injections of bevacizumab with a dose of 1.25 mg will be performed at one-month intervals. In this group, the interferon α 2b drop (1 MU/Ml) starts immediately after the first injection, and patients use one drop in the affected eye every 6 hours for three months.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Torfeh hospital
**Full name of responsible person**
Mahdi noori
**Street address**
Torfeh Hospital, Ibn Sina Street
**City**
Tehran
**Province**
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**Postal code**
1149847514
**Phone**
+98 21 7762 6550
**Email**
torfeHospital@sbmu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Mahdi noori
**Street address**
Arabi Ave, Daneshjoo Blvd, Velenjak
**City**
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**Province**
Tehran
**Postal code**
19839-63113
**Phone**
+98 21 7762 6550
**Email**
drmahdinoori@gmail.com
**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**
Private
**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**
Mahdi noori
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Ophthalmology
**Street address**
NO.5, Mostajabi Street, Iran Street
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
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**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahdi noori

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

**Street address**

No. 5, Mostajabi Alley, Iran St

**City**

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**Province**

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**Email**

Drmahdinoori@gmail.com

## 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**

All data can be shared after de-identifying individuals

**When the data will become available and for how long**

After finishing the study

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

For further research

**From where data/document is obtainable**

In order to receive the documents, please contact the person in charge of the project (Dr. Mehdi Nouri) (working at Torfeh Hospital) in person or by phone (mobile number 09122000493).

**What processes are involved for a request to access data/document**

After contacting the official (Mahdi Noori), the requested documents will be sent to the requester

**Comments**