

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effect of Interferon Alfa-2b in combination with intra-vitreous 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-vitreous 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/MI) 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 μ m; 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-vitreous 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/MI) 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

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1149847514

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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

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19839-63113

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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

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

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NO.5, Mostajabi Street, Iran Street

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Mahdi noori

Position

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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

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Position

resident

Latest degree

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Other areas of specialty/work

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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

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