

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of clinical outcomes after combined therapy of bevacizumab intravitreal injection and topical diclofenac with bevacizumab intravitreal injection alone in diabetic macular edema

Protocol summary

Study aim

Comparison of clinical outcomes after combined therapy of bevacizumab intravitreal injection and topical diclofenac with bevacizumab intravitreal injection alone in diabetic macular edema

Design

An open-label randomized clinical trial with parallel groups and phase 3 that will be conducted on 50 patients. Patients will be assigned to one of the intervention or control groups using the block randomization method, based on the generated-computer numbers by the random allocation software.

Settings and conduct

In this study, patients with non-proliferative diabetic retinopathy and diabetic macular edema in Urmia Imam Khomeini Hospital will be included. Patients in both intervention and control groups will receive standard treatment. In the intervention group, in addition to the standard treatment, diclofenac 1% topical drops will be prescribed. The study will be done as open label study.

Participants/Inclusion and exclusion criteria

In this study, 50 patients over 18 years of age with non-proliferative diabetic retinopathy and diabetic macular edema will be included. Patients with glaucoma, history of laser therapy, patients with media opacity, infection and inflammation of the anterior segment of the eye will not be included in the study.

Intervention groups

All patients will undergo standard treatment, which includes intravitreal injection of 1.25 mg of bevacizumab at the first visit and in the first, second and third months. Patients in the control group will receive standard treatment only. Patients in the intervention group, in addition to receiving the standard treatment will take 1 drop of topical diclofenac 1% 4 times a day.

Main outcome variables

Macula central thickness ; Visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220423054625N1**

Registration date: **2023-10-28, 1402/08/06**

Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**

Update count: **0**

Registration date

2023-10-28, 1402/08/06

Registrant information

Name

Ghader Motarjemizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3365 0824

Email address

gmotarjemizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcomes after combined therapy of bevacizumab intravitreal injection and topical diclofenac with bevacizumab intravitreal injection alone in diabetic macular edema

Public title

Investigating the effect of topical diclofenac in diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients with non-proliferative diabetic retinopathy and diabetic macular edema Age over 18 years

Exclusion criteria:

Glaucoma patients Patients with a history of laser therapy Patients with significant media opacity Infection and inflammation of the anterior chamber of the eye

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to one of the intervention or control groups using computer-generated numbers produced by the Random allocation software. Thus, in this software, the number of groups and the total sample size will be entered, and then the "randomization" will be implemented in the block section. Then, the computer-generated number list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups. Thus, the randomization process will continue until the final sample size is reached.

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 Imam Khomeini University hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.UMSU.HIMAM.REC.1402.047

Health conditions studied

1

Description of health condition studied

Diabetic macular edema

ICD-10 code

E08.331

ICD-10 code description

Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema

Primary outcomes

1

Description

Macula central thickness

Timepoint

Before the intervention and one and three months after the intervention

Method of measurement

Optical Coherence Tomography (OCT)

2

Description

Visual acuity

Timepoint

Before the intervention and one and three months after the intervention

Method of measurement

Snellen chart

Secondary outcomes

1

Description

Intraocular pressure

Timepoint

Before the intervention and one and three months after the intervention
Method of measurement
Tonometer

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to receiving the standard treatment, which includes intravitreal injection of 1.25 mg of bevacizumab at the first visit and in the first, second and third months, will take 1 drop of topical diclofenac 1% 4 times a day.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive the only standard treatment that includes intravitreal injection of 1.25 mg bevacizumab at the first visit and in the first, second and third months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Gader mtarjemizadeh

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57154-89397

Phone

+98 44 3345 7286

Email

gmotarjemizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

Street address

Urmia University of Medical Sciences, Resalat Ave,

Jahad Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 3009

Email

gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Gader Motarjemizadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

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Province

West Azarbaijan

Postal code

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Phone

+98 44 3245 7286

Email

gmotarjemizadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences
Full name of responsible person
Dr. Gader Motarjemizadeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd,
Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
57154-89397
Phone
+98 44 3345 7286
Email
gmotarjemizadeh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Gader Motarjemizadeh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Imam Khomeini hospital, Ershad Ave, Modarres Blvd,
Urmia, Iran.
City
Urmia

Province
West Azarbaijan
Postal code
57154-89397
Phone
+98 44 3345 7286
Email
gmotarjemizadeh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

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 the article is published

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

The data can be accessed as an Excel file and the results as a printed article.

From where data/document is obtainable

Corresponding author

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

By email address of the corresponding author:
gmotarjemizadeh@gmail.com

Comments