

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Evaluation of the effect of doxium on vision and macular thickness in patients with mild to moderate diabetic retinopathy

Protocol summary

Study aim

Determining the Effect of doxium Supplementation in Diabetic Retinopathy Determine the effect of doxium supplements on mild to severe diabetic retinopathy according to the thickness of the macula and vision

Design

Clinical trial with interventional and control group, community-based and pragmatic, with parallel groups, blinded two-way

Settings and conduct

Patients with type 2 diabetes with a minimum age of 18years are randomized by questioner in two groups by randomization software. Patients are divided into two groups. Patients in the target group receive doxium 50 mg per day and in placebo group, patients receive a placebo capsule for 6 months

Participants/Inclusion and exclusion criteria

Patients older than 18 years old, with mild to severe diabetic retinopathy Exclusion: patients with other co-morbidities, patients with a history of previous eye surgery, pregnancy, and lactation

Intervention groups

calcium dobisulate (doxium) capsules 500 mg, orally , three times in one day for three months

Main outcome variables

Macular thickness Ocular equity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220817055729N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Zahra Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3223 4897

Email address

zahra0khodadadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of doxium on vision and macular thickness in patients with mild to moderate diabetic retinopathy

Public title

doxium and retinopathy in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-proliferative diabetic retinopathy

Exclusion criteria:

other systemic disease except for diabetes Other comorbid conditions such as CNV, RVO, Glaucoma etc. Pregnancy Lactation The history of severe psychiatric illnesses such as schizophrenia, mood disorders, borderline disorders.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples of the participants in the study were randomly divided into two intervention and control groups using computer randomization software. The way of randomization in the groups will be that each patient is given a code and the codes are entered Microsoft Excel 2010 software and by executing the Randomization command and defining two groups, the software randomly places the codes in two separate groups. Then the output codes of the software will be placed in two groups 1 (intervention) and 2 (placebo).

Blinding (investigator's opinion)

Double blinded

Blinding description

Each eye was randomly assigned to receive one group of the medication. All preparations were individually prepared for each patient and patients and investigators were kept blinded to the randomized allocation and details of series of the medications throughout the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of medical science Ethical comitte

Street address

Resalat St.

City

Urmia

Province

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Postal code

5714783734

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.UMSU.HIMAM.REC.1400.014

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy

ICD-10 code

H36

ICD-10 code description

Retinal disorders in diseases classified elsewhere

Primary outcomes

1

Description

macular thickness

Timepoint

before and 6 months of treatment

Method of measurement

Macular OCT (Optical Coherence Tomography)

2

Description

Visual Equity

Timepoint

before and 6 months of treatment

Method of measurement

Snellen chart

Secondary outcomes

empty

Intervention groups

1

Description

50 mg of oral capsule doxium (Om Pharma, Switzerland) once a days for 180 days (maximum duration of intervention is 180 days)

Category

Treatment - Drugs

2

Description

Control group: simulating placebo capsule for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomayni Hospital

Full name of responsible person

Ghader Motarjemizadeh

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Ershad St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Gholamhossein Farjah

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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

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

Morteza Salimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Zahra Khodadadi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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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

The study aim will be described to all participants

When the data will become available and for how long

Hospital authorities for 1 year

To whom data/document is available

Hospital authorities

Under which criteria data/document could be used

Formal written permission form from the hospital

From where data/document is obtainable

Online via corresponding author email

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

Taking formal permission form from hospital with hospital authorities signature should be sent to corresponding author

Comments