Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral calcium dobisulate (doxium) on macular thickness in diabetic retinopathy and clinicaly significant macular edema(CSME)

Protocol summary

Summary

This study is a randomized, non-blinded, placebo-controlled single-center trial .All patients with non-proliferative diabetic retinopathy entry criteria with clinically significant macular edema and retinal referred to Imam Khomeini hospital of Ahwaz..patients with History of previous treatment for clinical significant macular edema such macular laser and intra viterus avastin injection ;Posterior segment truma ;The need for subsequent surgery of the eye, such as cataract surgery or vitreoretinal ;Clinical evaluation is not possible or where 0CT or FA Like intense opacity media; despite previous pathology such as retinal vascular occlusion, AMD...; History of previous intraocular surgery; Patients with visual acuity less than 1/10 were to study included. In this study 40 patients referred to the eye clinic of Ahvaz Imam Khomeini hospital with non-proliferative diabetic retinopathy and clinically significant macular edema were excluded and Fluorescein angiography to examine retinal leak fluid ; Coherence optical tomography(OCT) is performed to determine the thickness of the retina.The visual acuity and intraocular pressure were measured.Patients with status of macular edema treatmented with macular photocoagulation(MPC) or intravitreal Avastin injection and then were randomized two groups;A group of 20 patients received three Doxium capsuls daily and the second group 20 patients received placebo capsules daily for three months ; after three months evaluated of retinal thickness ;visual acuity and intraocular pressure in both groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012091610852N1**
Registration date: **2013-04-21, 1392/02/01**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-04-21, 1392/02/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral calcium dobisulate (doxium) on macular thickness in diabetic retinopathy and clinicaly significant macular edema(CSME)

Public title

The effect of doxium on retial thickness in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All patients with non prolifrative diabetic retinopathy and clinical significant macular edema refered to retinal clinic emam khomini hospital ,, ***Exclusion critreria ::History of previous treatment for clinical significant macular edema such macular laser and intra viterus avastin injection ;Posterior segment trauma ;The need for subsequent surgery of the eye, such as cataract surgery or vitreoretinal ;Clinical evaluation is not possible or where 0CT or FA Like intense opacity media; despite previous pathology such as retinal vascular occlusion, AMD...; History of previous intraocular surgery; Patients with visual acuity less than 1/10

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz bolvar Golestan

City

Ahvaz

Postal code

15794-61357

Approval date

2012-05-19, 1391/02/30

Ethics committee reference number

ETH-469

Health conditions studied

1

Description of health condition studied

Diabets melitus

ICD-10 code

H36

ICD-10 code description

Diabetic retinopathy

Primary outcomes

1

Description

macular thickness

Timepoint

befor and 3 month of treatment

Method of measurement

OCT

Secondary outcomes

1

Description

visual acuity

Timepoint

before and 3 month after treatment

Method of measurement

snelen chart

2

Description

intra ocular pressure

Timepoint

before and 3 month after treatment

Method of measurement

goldman tonometry

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Placebo capsules, orally ,three times daily for three months.

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomini hospital of ahvaz
Full name of responsible person
Akbar takhtaeayan
Street address
Street, 24 meters Ahvaz Imam Khomeini hospital
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Mostafa Feghhi
Street address
Ahvaz bolvar daneshgah
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty