Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of treatment of borderline hypercholesterolemia on risk of macular edema

Protocol summary

Summary

The aim of this study was to evaluate the effect of borderline hypercholesterolemia therapy in preventing the development of macular edema and diabetic retinopathy. Inclusion criteria is Diabetic retinopathy and Borderline hypercholesterolemia and exclusion Criteria is CSME macular edema and proliferative Diabetic retinopathy. the sample size is 84 patients (42 patients in each groups). Patients in the intervention group received daily atorvastatin 20mg for 3 months and the control group patients were given placebo daily for 3 months. The main outcome of this trial was macular edema.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709207466N5**
Registration date: **2017-10-31, 1396/08/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-31, 1396/08/09

Registrant information

Name
Reza Rezaei
Name of organization / entity
Ophtalmologist
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Research Deputy of Arak University Of Medical Sciences

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2017-09-23, 1396/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of treatment of borderline hypercholesterolemia on risk of macular edema

Public title

The effect of treatment of hypercholesterolemia on risk of macular edema
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Diabetic retinopathy; Borderline hypercholesterolemia; and having informed consent; Exclusion Criteria: CSME macular edema; proliferative Diabetic retinopathy;
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **82**
Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij Square, Arak, Iran
City
Arak
Postal code
Approval date
2016-02-15, 1394/11/26
Ethics committee reference number
IR.Arak.mu.ac.1394.302

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E10, E11,
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Macular Edema
Timepoint
Baseline, 3 Months later
Method of measurement
Test

Secondary outcomes

1

Description
Retinopathy
Timepoint
Baseline, 3 months Later
Method of measurement
Test

Intervention groups

1

Description
Daily, for 3 months, Atorvastatin 20 mg
Category
Treatment - Drugs

2

Description
Daily, for 3 months, Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital
Full name of responsible person
Dr Reza Rezaei
Street address
Amir Kabir Hospital, Vali-e Asr Street, Arak, Iran
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad arjomandzadegan
Street address
Arak University of Medical Sciences, Basij Sq., Arak, Iran
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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
Arak 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

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Ali Arash Anoushirvani

Position
Deputy of Research

Other areas of specialty/work

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Person responsible for scientific inquiries

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Ophthalmology, Assistant Prof

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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