Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of coenzyme Q10 and placebo on blood inflammatory and oxidant factors and beta-secretase activity levels in diabetic retinopathy patients

Protocol summary

Study aim

The aim of this study was to investigate the role of coenzyme Q10 in improve of Inflammatory and oxidative status and beta-secretase level in diabetic retinopathy patients.

Design

At the beginning of the study cognition status as well as serum beta-secretase levels and inflammatory and oxidant and antioxidant status of patients are evaluated. Treatment for three month in two groups:1) oral coenzyme Q10,200 mg daily and 2)Placebo will be done. At the end, the mentioned factors will be measured again and possible changes will be analyzed based on statistical calculations.

Settings and conduct

Cognitive status will be assessed using standard questionnaires. serum Beta-secretase levels and oxidation status will be determined by the relevant kits according to approved protocols. The study will be performed at Taban eye clinic in Qom Province.

Participants/Inclusion and exclusion criteria

Age between 40 and 75 years Blood pressure and glucose under control Adequate level of awareness and cognition exclude : neurological disease such as Alzheimer's, Parkinson's, cognitive impairment and MS. irreversible other eye disease such as glaucoma, cataracts, etc. Consumption of other antioxidant drugs such as vitamins E, C and A, etc. Taking immunosuppressive drugs for the past two months Patients with uncontrolled diabetes and Hypertension

Intervention groups

1)Coenzyme Q10 ,n=32 2)Placebo ,n=32

Main outcome variables

Inflammatory and oxidant factors and beta secretase activity levels of serum

General information

Reason for update

change in proposal For operational and feasibility reasons

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028046N2**
Registration date: **2022-03-18, 1400/12/27**
Registration timing: **prospective**

Last update: **2025-05-12, 1404/02/22**
Update count: **2**

Registration date

2022-03-18, 1400/12/27

Registrant information

Name

Mohammad Hossein Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3252 0182

Email address

mhsharif2013@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effect of coenzyme Q10 and placebo on blood inflammatory and oxidant factors and beta-secretase activity levels in diabetic retinopathy patients

Public title
Evaluation the effect of coenzyme Q10 on blood inflammatory and oxidant factors and beta-secretase activity levels in diabetic retinopathy patients

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
diabetic retinopathy patients
Exclusion criteria:
Other effective ocular disease and neurological diseases such as Alzheimer's and MS

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the method of random allocation rule, 32 balls called treatment group and 32 balls called placebo are mixed with each other and randomly removed one by one. The removed ball will not be replaced.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be duble blinded. Patients will be blinded to the type of intervention and the researcher who must evaluate and record the data will be blinded to the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Pajoohesh

City
Hamedan

Province
Hamadan

Postal code
6517838736

Approval date
2022-03-06, 1400/12/15

Ethics committee reference number
IR.UMSHA.REC.1400.969

Health conditions studied

1

Description of health condition studied
Diabetic Retinopathy

ICD-10 code
E08.31

ICD-10 code description
Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy

Primary outcomes

1

Description
Inflammatory/Anti Inflammatory factors

Timepoint
pre and post Treatment

Method of measurement
Elisa Kits

2

Description
Oxidant /Anti Oxidant Factors

Timepoint
pre and post Treatment

Method of measurement
Elisa kits

3

Description
serum Beta secretase activity

Timepoint
pre and post Treatment

Method of measurement
Elisa Kit

Secondary outcomes

1

Description

Blood pressure

Timepoint

pre and post Treatment

Method of measurement

Standard Barometer

Intervention groups

1

Description

Intervention group:Patients will be treated with Coenzyme Q10 soft gel prepared from jalinus Pharmaceutical Company (Tehran-Iran),orally (200mg), daily for 120 days

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taban Eye Clinic

Full name of responsible person

Fatemeh Javadian

Street address

Boo Ali Sina

City

Qom

Province

Ghoum

Postal code

3716615198

Phone

+98 25 3294 5000

Email

tabanCl-Qom@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abdolrahman Sarihi

Street address

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Province

Hamadan

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sarihi@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abdolrahman Sarihi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for updating data

Contact

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Full name of responsible person

Mohamad Hossein Sharif

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available