

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The prophylactic effect of co-enzyme Q10 versus placebo on contrast-induced nephropathy in patients with diabetes mellitus type II: a double-blind randomized clinical trial study

Protocol summary

Study aim

To assess the prophylactic effect of coenzyme Q10 versus placebo on contrast-induced nephropathy in patients with diabetes mellitus type II

Design

This is a double-blind randomized clinical trial, phase II, in which 104 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with diabetes mellitus type II referring to the Shahid Beheshti Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Diabetes mellitus type II for at least one year, Need for CT scan with contrast material, Microalbuminuria or macroalbuminuria Exclusion criteria: Pregnancy or breastfeeding, Receiving contrast material last week, Taking antioxidants last week, Kidney activity instability, Sensitivity to iodinated contrast agents

Intervention groups

Intervention group: Coenzyme Q10 100 mg capsule (manufactured by Hakimian Teb Pharmaceutical Company) daily one day before angiography until 6 days after Control group: Placebo capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily one day before angiography until 6 days after

Main outcome variables

Primary outcome: Serum creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N337**

Registration date: **2020-01-29, 1398/11/09**

Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**

Update count: **0**

Registration date

2020-01-29, 1398/11/09

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The prophylactic effect of co-enzyme Q10 versus placebo on contrast-induced nephropathy in patients with diabetes mellitus type II: a double-blind randomized clinical trial study

Public title

The prophylactic effect of co-enzyme Q10 versus placebo on contrast-induced nephropathy in patients with diabetes mellitus type II

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years, Diabetes mellitus type II for at least one year, Need for CT scan with contrast material, Microalbuminuria or macroalbuminuria

Exclusion criteria:

Pregnancy or breastfeeding, Receiving contrast material last week, Taking antioxidants last week, Kidney activity instability, Sensitivity to iodinated contrast agents

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

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

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-01-11, 1398/10/21

Ethics committee reference number

IR.UMSHA.REC.1398.875

Health conditions studied**1****Description of health condition studied**

Diabetes mellitus with nephropathy

ICD-10 code

E08.21

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes**1****Description**

Serum creatinine

Timepoint

Daily before the intervention and 7 days after that

Method of measurement

By laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Coenzyme Q10 100 mg capsule (manufactured by Hakimian Teb Pharmaceutical Company) daily one day before angiography until 6 days after

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) daily one day before angiography until 6 days after

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan city

Full name of responsible person

Ashkan Karbasi

Street address

Shahid Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

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

Ashkan Karbasi

Position

PhD Student of Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

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Professor of Epidemiology

Latest degree

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Other areas of specialty/work

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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