

# 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)

##### Phone

+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.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0283

##### Email

akarbasi@gmx.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

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##### Phone

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#### Email

info.research@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

Ashkan Karbasi

##### Position

PhD Student of Biochemistry

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Biochemistry

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Heidar Tayebnia

##### Position

Biochemist

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Biochemistry

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tayebinia@umsha.ac.ir

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

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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