

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of coenzyme Q10 versus placebo on the prevention of contrast medium-induced nephropathy in patients undergoing primary angioplasty: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of coenzyme Q10 versus placebo on the prevention of contrast medium-induced nephropathy in patients undergoing primary angioplasty

Design

This is a double-blind randomized clinical trial, phase III, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients undergoing primary angioplasty referring to the Farshchian Heart 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 18 to 75 years; Symptoms of persistent myocardial ischemia for at least 30 minutes; Less than 12 hours after the onset of heart attack symptoms; Increased ST segment on electrocardiogram; Treated with primary angioplasty; Exclusion criteria: Consumption of any antioxidants in the past month; Indication of cardiac bypass surgery; History of myocardial infarction or angioplasty; Indication of thrombolytic therapy; Cardiogenic shock; History of heart failure; Advanced liver failure or autoimmune or inflammatory diseases

Intervention groups

Intervention group: Routine treatment (angiotensin inhibitors, statin, anti-platelet, beta-blockers) plus one capsule Q10 400 mg (manufactured by Dana Pharmaceutical Co.) single dose immediately before angioplasty and then 200 mg every 12 hours for 3 days
Control group: Routine treatment (angiotensin inhibitors, statin, anti-platelet, beta-blockers) plus one capsule

placebo as a single-dose immediately before angioplasty and then one capsule every 12 hours for 3 days

Main outcome variables

Primary outcome: Nephropathy Secondary outcome: Serum level of CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N414**

Registration date: **2021-12-29, 1400/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-29, 1400/10/08**

Update count: **0**

Registration date

2021-12-29, 1400/10/08

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-25, 1400/10/04

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of coenzyme Q10 versus placebo on the prevention of contrast medium-induced nephropathy in patients undergoing primary angioplasty: a double-blind randomized clinical trial

Public title

Effect of coenzyme Q10 versus placebo on the prevention of contrast medium-induced nephropathy in patients undergoing primary angioplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 75 years; Symptoms of persistent myocardial ischemia for at least 30 minutes; Less than 12 hours after the onset of heart attack symptoms; Increased ST segment on electrocardiogram; Treated with primary angioplasty;

Exclusion criteria:

Consumption of any antioxidants in the past month; Indication of cardiac bypass surgery; History of myocardial infarction or angioplasty; Indication of thrombolytic therapy; Cardiogenic shock; History of heart failure; Advanced liver failure or autoimmune or inflammatory diseases

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

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 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

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Postal code

6517838695

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.UMSHA.REC.1400.698

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

Angioplasty

ICD-10 code

Z98.6

ICD-10 code description

Angioplasty status

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

Nephropathy

Timepoint

Before the intervention and 24, 48, 72 hours after the intervention

Method of measurement

By measuring serum levels of BUN, creatinine and Estimated glomerular filtration rate (eGFR)

Secondary outcomes

1

Description

Serum level of CRP

Timepoint

Before the intervention and 24, 48, 72 hours

Method of measurement

After the intervention by laboratory test

Intervention groups

1

Description

Intervention group: Routine treatment (angiotensin inhibitors, statin, anti-plaquet, beta-blockers) plus one capsule Q10 400 mg (manufactured by Dana Pharmaceutical Co.) single dose immediately before angioplasty and then 200 mg every 12 hours for 3 days

Category

Treatment - Drugs

2

Description

Control group: Routine treatment (angiotensin inhibitors, statin, anti-plaquet, beta-blockers) plus one capsule placebo as a single-dose immediately before angioplasty and then one capsule every 12 hours for 3 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Ayeshah Rahmani

Street address

Farshchian Heart Hospital, Shahid Fahmideh 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. Reza Shokoohi

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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

Ayeshah Rahmani

Position

Student of Pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Contact

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Full name of responsible person

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Pharmacologist

Latest degree

Ph.D.

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Person responsible for updating data

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Full name of responsible person

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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