Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-placket, 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-placket, 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

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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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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
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Hamadan
Province
Hamadan
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-placket, 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-placket, 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
Ayesheh Rahmani
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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