Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Coenzyme Q10 as an adjunct therapy versus placebo on para-clinical signs after primary angioplasty of coronary artery in acute ST-elevation myocardial infarction: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of Coenzyme Q10 as an adjunct therapy versus placebo on para-clinical signs after primary angioplasty of coronary artery in acute ST-elevation myocardial infarction

Design

This is a double-blind randomized clinical trial, in which 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with acute ST-elevation myocardial infarction 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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years; Myocardial ischemia for at least 30 minutes; Myocardial infarction disease in the last 12 hours; Elevated ST segment on electrocardiogram; Angioplasty for the first time; Exclusion criteria: Candidate for emergency coronary bypass surgery; History of heart attack or heart failure or angioplasty; Indication for thrombolytic therapy; Cardiogenic shock; Liver failure; Autoimmune diseases or inflammation; Taking antioxidant medicines in the past month;

Intervention groups

Intervention group: Routine treatment plus injection of Coenzyme Q10 400 mg (manufactured by Dana pharmaceutical Co.) immediately after angioplasty and then 200 mg every 12 hours for 28 days Control group: Routine treatment plus injection of placebo (normal saline) 4 ml immediately after angioplasty and then 2 ml every 12 hours for 28 days

Main outcome variables

Primary outcome: Serum level of troponin; Serum level of CK-MB; Thrombolysis; Myocardial blushing grade; ST-segment resolution; Left ventricular ejection fraction Secondary outcome: Adverse effects (heart failure, cardiogenic shock, re-infarction, and death)

General information

Reason for update

Change in duration of treatment and sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N407**
Registration date: **2021-11-18, 1400/08/27**
Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**
Update count: **1**

Registration date

2021-11-18, 1400/08/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date
2023-02-04, 1401/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Coenzyme Q10 as an adjunct therapy versus placebo on para-clinical signs after primary angioplasty of coronary artery in acute ST-elevation myocardial infarction: a double-blind randomized clinical trial

Public title
Effect of Coenzyme Q10 as an adjunct therapy versus placebo on para-clinical signs after primary angioplasty of coronary artery in acute ST-elevation myocardial infarction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 80 years; Myocardial ischemia for at least 30 minutes; Myocardial infarction disease in the last 12 hours; Elevated ST segment on electrocardiogram; Angioplasty for the first time;
Exclusion criteria:
Candidate for emergency coronary bypass surgery; History of heart attack or heart failure or angioplasty; Indication for thrombolytic therapy; Cardiogenic shock; Liver failure; Autoimmune diseases or inflammation; Taking antioxidant medicines in the past month;
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
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 medication and placebo will be injected having perfectly the same shape. 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
2021-10-31, 1400/08/09
Ethics committee reference number
IR.UMSHA.REC.1400.623

Health conditions studied

1

Description of health condition studied
ST elevation myocardial infarction
ICD-10 code
I21.0
ICD-10 code description
ST elevation (STEMI) myocardial infarction of anterior wall

Primary outcomes

1

Description
The serum level of troponin
Timepoint
Before angioplasty and 6, 12, 24, 48, and 72 hours after that
Method of measurement
By laboratory test

2

Description
The serum level of CK-MB
Timepoint
Before angioplasty and 6, 12, 24, 48, and 72 hours after that
Method of measurement
By laboratory test

3

Description
Thrombolysis in myocardial infarction (TIMI) flow grade
Timepoint
After angioplasty
Method of measurement
By laboratory test

4

Description
Myocardial blushing grade (MBG)
Timepoint
After angioplasty
Method of measurement
By echocardiography

5

Description
ST-segment resolution
Timepoint
Immediately and 24 hours after angioplasty
Method of measurement
By echocardiography

6

Description
Left ventricular ejection fraction
Timepoint
30 days after angioplasty
Method of measurement
By echocardiography

Secondary outcomes

1

Description
Adverse effects (heart failure, cardiogenic shock, re-infarction, and death)
Timepoint
during the treatment period
Method of measurement
with taking history

Intervention groups

1

Description
Intervention group: Routine treatment plus injection of Coenzyme Q10 400 mg (manufactured by Dana pharmaceutical Co.) immediately after angioplasty and then 200 mg every 12 hours for 28 days
Category
Treatment - Drugs

2

Description
Control group: Routine treatment plus injection of placebo (normal saline) 4 ml immediately after angioplasty and then 2 ml every 12 hours for 28 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Kimia Shirmohammadi
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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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Student of Pharmacy
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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