

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the protective effect of N-Acetylcysteine versus placebo on the heart of diabetic patients undergoing CABG: a triple blind randomized clinical trial

Protocol summary

Study aim

To assess the protective effect of N-Acetylcysteine versus placebo on the heart of diabetic patients undergoing CABG

Design

A triple blind randomized clinical trial

Settings and conduct

The eligible diabetic patients who will undergo CABG refer to Farshchian Heart Hospital during the study period will be enrolled into the trial

Participants/inclusion and exclusion criteria

Inclusion criteria: Age of 45 to 75 years Male gender Diabetic Candidate for undergoing CABG Cardiac index at least 2.5 L/m² Exclusion criteria: Myocardial infarction after CABG Moderate to severe Valvular disorder Taking inotropic medication for a long time before or after surgery Arm circumference larger than barometric cuff

Intervention groups

Intervention group: Intravenous injection of N-Acetylcysteine 3 mg/kg single dose one hour before surgery. Control group: Intravenous injection of normal saline 3 ml/kg single dose one hour before surgery.

Main outcome variables

Assessing cardiac ejection fraction before and 3 days after surgery using transthoracic echocardiography. Assessing cardiac index before and 3 days after surgery using transthoracic echocardiography.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N202**

Registration date: **2017-12-31, 1396/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-31, 1396/10/10**

Update count: **0**

Registration date

2017-12-31, 1396/10/10

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

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-05-05, 1396/02/15

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

empty

Scientific title

Evaluation of the protective effect of N-Acetylcysteine versus placebo on the heart of diabetic patients undergoing CABG: a triple blind randomized clinical trial

Public title

Evaluation of the protective effect of N-Acetylcysteine

versus placebo on the heart of diabetic patients undergoing CABG

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age of 45 to 75 years Male gender Diabetic Candidate for undergoing CABG Cardiac index at least 2.5 L/m2
Exclusion criteria:
 Myocardial infarction after CABG Moderate to severe Valvular disorder Taking inotropic medication for a long time before or after surgery Arm circumference larger than barometric cuff

Age
From **45 years** old to **75 years** old

Gender
Male

Phase
2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **240**
 Actual sample size reached: **240**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through drawing of lots.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple 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
 2017-04-22, 1396/02/02
Ethics committee reference number
 IR.UMSHA.REC.1396.77

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft

ICD-10 code

I25.70

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris

Primary outcomes

1

Description

Assessing cardiac ejection fraction

Timepoint

before and 3 days after surgery

Method of measurement

using transthoracic echocardiography

2

Description

Assessing cardiac index

Timepoint

before and 3 days after surgery

Method of measurement

using transthoracic echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous injection of N-Acetylcysteine 3 mg/kg single dose one hour before surgery.

Category

Treatment - Drugs

2

Description

Control group: Intravenous injection of normal saline 3

ml/kg single dose one hour before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Heart Hospital
Full name of responsible person
Dr Zahra Mohammadzadeh Vijeh
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
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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
Dr Zahra Mohammadzadeh Vijeh
Position
Resident of Anesthesiology
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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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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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