

# 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/m<sup>2</sup> 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

###### Email address

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 Vije  
**Street address**  
Farshchian Heart Hospital, Shahid Fahmideh Ave.  
**City**  
Hamadan  
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**Postal code**  
6517838695  
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+98 81 3838 1740  
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mohammadzade84@gmail.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**  
Farshchian Heart Hospital, Shahid Fahmideh Ave.  
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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**  
Dr Zahra Mohammadzadeh Vije  
**Position**  
Resident of Anesthesiology  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
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mohammadzade84@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr Ahmad Reza Salim Bahrami  
**Position**  
Anesthesiologist  
**Latest degree**  
Specialist  
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## 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

**Street address**

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Medical Sciences, Shahid Fahmideh Ave

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poorolajal@umsha.ac.ir

**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