

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of cardioprotective effects of “N-acetylcysteine” to cardioplegia and “glucose-insulin-potassium” during coronary artery bypass grafting in patient candidate for CABG

Protocol summary

Summary

In a double-blind randomized clinical trial, 60 elective CABG patients with EF < 50% will be evaluated. The patients will be numbered according to their reference to the Heart Center of Mazandaran (Iran) and their arrangements in the operation list. They will be randomly allocated to 2 groups of 30 by a computer program to receive either GIK (group G) or NAC (group N). In group G, 10 cc/h of GIK solution will be infused constantly during the surgery. Group N will be injected with a cardioplegic solution containing 200 mg NAC. Normal saline will be used as placebo in both groups (injected in group G and infused constantly in group N) to prevent the surgical team from identifying the drugs. A cardiopulmonary bypass pump will be used for all cases in both groups. Subjects will be excluded in case of requiring intra-aortic balloon pump during the operation, prolonged cross-clamp period of 1.5 hours or more, and sensitivity to NAC. EF, Frequency of arrhythmia, need for inotropic drugs during and after the operation, need for shock and pacemaker, commencement of normal heart rhythm, postoperative levels of cardiac enzymes, ECG changes, central venous pressure (CVP), and duration of hospital and intensive care unit (ICU) stay will be also recorded and compared between the 2 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211062883N3**
Registration date: **2012-11-30, 1391/09/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

Name

Mohammadreza Habibi

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 15 1222 3023

Email address

mhabibi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services Deputy of Research

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of cardioprotective effects of “N-acetylcysteine” to cardioplegia and “glucose-insulin-potassium” during coronary artery bypass grafting in patient candidate for CABG

Public title

Protecting effect of N-acetylcysteine on myocardium during

CABG

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients who candidate for CABG with EF below 50% at Mazandaran Heart Center Exclusion criteria: Valvular heart diseases; renal failure; liver disease; cross clamp time more than 1:30 min & use of intraaortic balloon pump

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences

Street address

serah Jouibar, Valiasr Ave.

City

Sari

Postal code

Approval date

2011-01-19, 1389/10/29

Ethics committee reference number

89128

Health conditions studied

1

Description of health condition studied

Atherosclerotic cardiovascular disease

ICD-10 code

I25.0

ICD-10 code description

Atherosclerotic cardiovascular disease

Primary outcomes

1

Description

ejection fraction of LV

Timepoint

before operation & 5 day after operation

Method of measurement

echocardiograph

Secondary outcomes

1

Description

arrhythmia

Timepoint

during operation & ICU stay

Method of measurement

monitor

Intervention groups

1

Description

Control group: infusion of GIK during operation

Category

Treatment - Drugs

2

Description

Intervention group: injection of N Acetylcystein with cardiopelagic solution

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemezahra Hospital

Full name of responsible person

Dr. Mohammadreza Habibi

Street address

Artesh Blv.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Full name of responsible person

Ahmad Ali Enayati

Street address

Deputy of Research, Moalem sq

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Habibi

Position

Assistant Professor; Fellowship of Cadiac Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty