

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of vitamin E and N-acetylcysteine on prevention of contrast-induced acute kidney injury after coronary catheterization in diabetic patients

Protocol summary

Study aim

Comparing the effect of vitamin E and N-acetylcysteine on prevention of contrast-induced acute kidney injury after coronary catheterization in diabetic patients referring to the Cardiac ward of Modarres Hospital

Design

A total of 300 patients were categorized into three groups (100 patients in each group). Group 1 received sodium chloride and placebo N-acetylcysteine and placebo vitamin E, group 2 received sodium chloride and placebo N-acetylcysteine and real vitamin E, and group 3 received sodium chloride and placebo vitamin E and real N-acetylcysteine; 12 hours before and 12 hours after angiography. After initial assessment and evaluating the inclusion criteria, they were informed about the study, and asked to sign the written informed consent. The demographic information of patients, including age, sex, risk factors, serum laboratory parameters were recorded in the study checklist. 48 hours after angiography the serum laboratory tests were repeated and the patients' creatinine was calculated.

Settings and conduct

Shahid Modarres Hospital

Participants/Inclusion and exclusion criteria

All patients with 1) stable coronary disease at risk of acute myocardial infarction, who required coronary artery intervention, 2) acute coronary syndrome who required coronary artery intervention, and 3) patients with history of diabetes mellitus

Intervention groups

Group 1 received sodium chloride and placebo N-acetylcysteine and placebo vitamin E, group 2 received sodium chloride and placebo N-acetylcysteine and real vitamin E, and group 3 received sodium chloride and placebo vitamin E and real N-acetylcysteine; 12 hours before and 12 hours after angiography

Main outcome variables

Increase in serum creatinine $>44 \mu\text{mol/L}$ or 0.5 mg/dL or 25% increase 48 hours after injection of contrast was considered as contrast-induced nephropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200417047114N1**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **retrospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

mina mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3327 1135

Email address

minamirzai29@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-02, 1398/02/12

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin E and N-acetylcysteine on prevention of contrast-induced acute kidney injury after coronary catheterization in diabetic patients

Public title

Vitamin E and N-acetylcysteine on prevention of contrast-induced acute kidney injury after coronary catheterization in diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with stable coronary disease at risk of acute myocardial infarction, who required coronary artery intervention (angiography) Patients with acute coronary syndrome, who required coronary artery intervention (angiography) Diabetic patients

Exclusion criteria:

Patients with hypersensitivity to contrast material Patients with cardiogenic shock Patients with pulmonary edema Patients with acute renal failure Patients with acute coronary syndrome who underwent angiography or angioplasty for the past 5 days Patients with recent injection of any contrast material (like radiologic interventions) Patients with history of dialysis Pregnant women Patients with acute myocardial infarction

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 300 patients were categorized into three groups randomly based on 1:1:1 ratio (100 patients in each group)

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants were blinded by giving placebo with similar appearance The clinician was blinded by labeling the drugs by A, B, and C The specialist evaluating patients' GFR was not aware of the group allocations The analyst was not aware of the group allocations, as the groups were named by A, B, and C

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.SBMU.MSR.REC.1398.199

Health conditions studied**1****Description of health condition studied**

Contrast-induced nephropathy

ICD-10 code**ICD-10 code description**

نفروپاتی

Primary outcomes**1****Description**

0.5 mg/dl increase in serum creatinine level or 25% compared to baseline was considered as contrast-induced nephropathy

Timepoint

Before and 48 hours after intervention

Method of measurement

Patients' serum test results

Secondary outcomes**1****Description**

The frequency of contrast-induced nephropathy

Timepoint

48 hours after intervention

Method of measurement

Patients' serum test results

Intervention groups

1

Description

Intervention group1: Sodium chloride + placebo N-acetylcysteine + real vitamin E

Category

Prevention

2

Description

Intervention group 2: Sodium chloride + real N-acetylcysteine + placebo vitamin E

Category

Prevention

3

Description

Control group: Sodium chloride + placebo N-acetylcysteine + placebo vitamin E

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Mina Mirzai

Street address

Kaj square

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Postal code

1998734383

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+98 21 2207 4087

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modarres@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahram Alamdari

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Yemen st. Shahid Chamran Highway

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Grant name

Grant code / Reference number

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

No

Title of funding source

Research Deputy of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mina Mirzai

Position

resident of internal medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Decision of my supervisor

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publication of the study results in form of article and
thesis

When the data will become available and for how long

The first six months of this year

To whom data/document is available

everyone

Under which criteria data/document could be used

under supervision of journal and university

From where data/document is obtainable

journal and university

What processes are involved for a request to access data/document

under supervision of journal and university

Comments