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 ach 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 Evitamin 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 Evitamin 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 µmol/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

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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
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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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1998734383
Phone
+98 21 2207 4087
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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
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Position
resident of internal medicine
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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