

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of N-acetylcysteine, Ascorbic acid and Normal saline effect in prevention of contrast-induced nephropathy on the patient's undergone coronary angiography

Protocol summary

Summary

Objectives: Considering the crucial role of appropriate preventative strategies in reducing the rate of contrast induced nephropathy (CIN) occurrence and its related morbidity and mortality, the effect of N-acetylcysteine (NAC), Ascorbic Acid (AA) and normal Saline will be investigated in the patient's undergone coronary angiography. Design: In this randomized single blind, clinical trial, Setting and conduct : 120 patients scheduled for elective coronary angiography with serum creatinine level more than 1.5mg/dl or GFR more than or equal 60 will be selected by convenience method and patients with Oliguria (<400cc/24hours), severe heart failure with left ventricular ejection fraction (LVEF) < 35%, contrast-agent hypersensitivity, pregnancy, lactation, acute renal failure, , Vitamin C supplements will exclude . Intervention : Selected patients will be allocated in three treatment groups randomly to receive oral NAC(600mg/BID) plus normal saline (100ml/hour) [group A] ,oral ascorbic acid (250 mg/BID) plus normal saline (100ml/hour) [group B] and normal saline (100ml/hour) [group C], respectively. Main outcome measures: Occurrence of CIN will be evaluated based of serum creatinine (Cr) and glomerular filtration rate (GFR) in three studied groups, before and 72hours after angiography procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050722134N1**

Registration date: **2015-06-16, 1394/03/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Mahtab Keshvari

Name of organization / entity

Cardiovascular Institution

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of N-acetylcysteine, Ascorbic acid and Normal saline effect in prevention of contrast-induced nephropathy on the patient's undergone coronary angiography

Public title

contrast-induced nephropathy and the patient's

undergone coronary angiography

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: creatinine level of >1.5mg/dl; glomerular filtration rate (GFR) \leq 60 Exclusion criteria: Oliguria (<400cc/24hours); severe heart failure with left ventricular ejection fraction (LVEF) < 35%; contrast-agent hypersensitivity; pregnancy; lactation; acute renal failure; Vitamin C supplements

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Blvarayt Ayatollah Kashani, Staff University, Building No. 2, Vice chancellor for research,Shahrekord

City

Shahrekord

Postal code

8815713471

Approval date

2010-05-18, 1389/02/28

Ethics committee reference number

934

Health conditions studied

1

Description of health condition studied

Acute nephritic syndrome

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Left ventricular failure

Primary outcomes

1

Description

creatinine

Timepoint

before and after angiography

Method of measurement

ELISA kit

2

Description

glomerular filtration

Timepoint

before and after angiography

Method of measurement

Were used average estimated glomerular filtration rate of clearance of endogenous or exogenous materials

Secondary outcomes

empty

Intervention groups

1

Description

group A:N-acetylcysteine (NAC)(600mg/BID) plus normal saline (100ml/hour).for 72hours

Category

Treatment - Drugs

2

Description

group B: ascorbic acid (250 mg/BID) plus normal saline (100ml/hour). for 72 hours

Category

Treatment - Drugs

3

Description

group C :normal saline (100ml/hour). for 72 hours

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hajar hospital

Full name of responsible person

Dr. Amrolali Ebrahimi

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Hajar hospital, Parastar street, Shahrekord

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Vice chancellor for research, Shahrekord University of Medical Sciences

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**

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Web page address

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