

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Intravenous and intracoronary Vitamin C for the Prevention of Periprocedural Myocardial Injury And Contrast-Induced Acute Kidney Injury in Patients Undergoing Primary Percutaneous Coronary Intervention.

Protocol summary

Summary

This interventional study will be conducted as a prospective, Single-center, randomized trial. 110 patients with Acute STEMI admitted to Tehran Heart Center since the April 2016 and scheduled for Primary PCI will be selected. All patients who meet the eligibility criteria with informed consent will be randomized in a 1:1 ratio to receive during surgical procedure an intravenous and intracoronary of Vitamin C or Placebo. In a group before angioplasty and stenting, three grams of vitamin C as a bolus intravenously in the emergency department and 96 mg of vitamin C intracoronary in cathlab after stenting in addition to other routine treatments will be administered and other groups will receive other routine treatments only. Blood samples will be collected in the study patients before and 6 and 18 hours after PCI to measure CK-MB and Troponin I and two groups will be compared. On the blood samples taken from these two groups for zero-hour clock and 6 clocks NGAI kit will be tested for prediction of contrast induced acute kidney injury.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706168698N21**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Intravenous and intracoronary Vitamin C for the Prevention of Periprocedural Myocardial Injury And Contrast-Induced Acute Kidney Injury in Patients Undergoing Primary Percutaneous Coronary Intervention.

Public title

Vitamin C and Percutaneous Coronary Intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Subjects (men or women) at least 18 years and less than 80 years of age; Ischemic discomfort ≥ 20 min and < 6 hours of duration; ST elevation ≥ 1 mm (≥ 0.1 mV) in two contiguous limb leads OR ≥ 2 mm (≥ 0.2 mV) in two contiguous precordial leads ; Planned primary PCI within 2 hours of hospital presentation; Planned or concomitant use of aspirin, clopidogrel, unfractionated heparin, and Glycoprotein IIb/IIIa inhibition with intent to stent the infarct-related artery; Informed consent able to be obtained
 Exclusion Criteria: Age ≥ 80 years; Cardiac arrest or arrhythmia requiring chest compressions or cardiopulmonary resuscitation; Current warfarin therapy; Known allergy or contraindication to fibrinolytics OR aspirin OR heparin OR clopidogrel; Patients with evidence of coronary collaterals (2-3 Rentrop) to the region at risk on previous coronary angiography (at the previous admission);Renal failure(creatinine >4.0 mg/dl).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not 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 Tehran University of Medical Sciences

Street address

No. 23, before Pour Sina St. - 16th Azar St. - Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2017-06-06, 1396/03/16

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

Acute myocardial infarction

ICD-10 code

I21.3

ICD-10 code description

Acute transmural myocardial infarction of unspecified site
 Transmural myocardial infarction NOS

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

myocardial infarction

Timepoint

before intervention

Method of measurement

clinical history and ECG

2**Description**

Troponin I

Timepoint

before and 6, 18 hour after PCI

Method of measurement

ELISA

3**Description**

Creatine Kinase-MB

Timepoint

before and 6,18 hour after PCI

Method of measurement

spectrophotometry

4**Description**

NGAL

Timepoint

before and 6 hour after PCI

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Moreover the routine treatment

before primary PCI and stenting of culprit lesion 3 gram of intravenous vitamin C bolus and after stenting 96 mg intracoronary will be inject.

Category

Treatment - Drugs

2**Description**

Control group: routine treatment will be do.

Category

Treatment - Drugs

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

Tehran Heart Center

Full name of responsible person**Street address****City**

Tehran

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

Vice Chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Yunesian

Street address

6th floor; Corner of Quds Street; Keshavarz Blvd

City

Tehran

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, Tehran 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**

Tehran Heart Center

Full name of responsible person

Azita Haj Hossein Talasaz

Position

PharmD, BCPS, AQ-Card

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Negar Shafaei Bajestani

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Resident in Clinical Pharmacy

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

Tehran University of Medical Sciences

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Position

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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