Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 compared. On the blood samples taken from these two groups for zero-hour clock and 6 clocks NGAl 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 (≥ 0.1mV) in two contiguous limb leads OR ≥ 2mm (≥0.2mV) 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 obtaine Exclusion Criteria: Age ≥80 years; Cardiac arrest or arrhythmia requiring chest compressions or cardiopulmonary resuscitation; Current warfarin therapy; Known allergy or contraindication to fibrinolvtics 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
IR.TUMS.PSRC.REC.1396.2529

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 intravenus 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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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