# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The Effect of preprocedural and intraprocedural Vitamin C Infusion on decrease Thrombolysis in myocardial infarction(TIMI) flow grade and Myocardial Perfusion Grade (MPG) for Patient Undergoing Primary Percutaneous coronary intervention( PCI)

## Protocol summary


**Summary**

This interventional study of elective clinical trial to study effect of Vitamin C on Coronary Reperfusion Indexes will be conducted in which 320 patients since the spring of 2016 on wards diagnosed with Acute STEMI for Primary PCI to catheterization ward of Tehran Heart Center introduced as a standard inclusion and exclusion criteria , with informed consent and the study will be selected. Patients on the basis of criteria defined quite similar in the two groups of 160 patients randomly divided and in a group before angioplasty and stenting, three grams of a bolus of vitamin c intravenously in the emergency department and 96 mg of the intracoronary also in cathlab after stenting in addition to other routine treatments will be administered through angioplasty and stenting and other groups will perform other routine treatments only . After angioplasty with re-injection of contrast agent, the flow grade (Thrombolysis In Myocardial Infarction (TIMI) and (MPG) Myocardial Perfusion Grade aimed at two groups will compare.on the blood samples taken from these two group for zero-hour clock and 6 clock the P-selectin kit will be tested for platelet aggregation.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201606048698N19**
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**

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Azita Hajhossein Talasaz
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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**

The Effect of preprocedural and intraprocedural Vitamin C Infusion on decrease Thrombolysis in myocardial infarction(TIMI) flow grade and Myocardial Perfusion Grade (MPG) for Patient Undergoing Primary Percutaneous coronary intervention( PCI)

**Public title**

The effect of vitamin C on acute MI in primary PCI setting

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria: Subjects (men or women) at least 18 years and less than 80 years of age; Ischemic discomfort ≥20 minutes and ≤6 hours of duration; ST elevation ≥1mm (≥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 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) .

**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: **320**

**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**

Ethic committee of Tehran University of Medical Science

**Street address**

building (1),Poursina Avenue, Qods Street, Enqelab Square.

**City**

Tehran

**Postal code**

**Approval date**

2016-11-13, 1395/08/23

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1395.1016

## 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

## Primary outcomes

### 1

**Description**

myocardial infarction

**Timepoint**

before intervention

**Method of measurement**

clinical history and ECG

### 2

**Description**

myocardial perfusion grade

**Timepoint**

after PCI

**Method of measurement**

by angiographic interpretation

### 3

**Description**

TIMI flow

**Timepoint**

after stenting

**Method of measurement**

by angiographic interpretation

### 4

**Description**

p selectin kit

**Timepoint**

one month

**Method of measurement**

ELISA

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Interventional group: moreover the routin treatment, before primary PCI and stenting of culprit lesion 3 gram of intravenus vitamin C bolusand after stenting 96 mg again will be inject.

**Category**
Treatment - Drugs

**2**

**Description**
Control group: routine treatement

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Tehran Heart Center

**Full name of responsible person**
Seyed Farshad Sadri Jokandan

**Street address**
North KargarAve , Tehran,Iran

**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**
Keshavarz blvd, Quds St, Tehran Province

**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 University of Medical Sciences

**Full name of responsible person**
Haj HoseinTalasaz Azita

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PharmD, BCPS, AQ-Card

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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*