

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of prophylactic intracoronary Adenosine infusion during primary percutaneous coronary intervention in Acute ST Elevation Myocardial infarction

#### Protocol summary

##### Summary

Objective: To assess the effect of prophylactic intracoronary adenosine infusion during primary percutaneous intervention in acute ST elevation myocardial infarction. Design: Randomized control trial. Setting: The eligible patients with acute ST elevation myocardial infarction who admitted to emergency room of Farshchian heart center during 2017-2018. Inclusion criteria: (a) ST elevation MI in ECG; (b) LAD and LCX lesion; (c) coronary lesion suitable for angioplasty; (d) TIMI flow 0-1. Exclusion criteria: (a) history of COPD or asthma; (b) patients who under treatment with dipyridamol; (c) Presentation with cardiogenic shock; (d) Patients who received fibrinolytic; (e) life expectancy less than 6 month; (f) stent thrombosis; (g) history of CABGs; (h) AV nodal block in first ECG; (i) TIMI flow 2-3 in angiography; (j) RCA lesion; (k) lack of patient satisfaction. Intervention: Two separated doses of 40 microgram adenosine in 10 ml normal saline 0.9% intracoronary infusion during primary PCI on LAD or LCX. Control: Two separated doses of Intracoronary 10 ml normal saline 0.9% infusion in left coronary system. Primary outcome: (a) ST elevation resolution; (b) TIMI flow; (c) level of CKMB and troponin. Secondary outcome: (a) inhospital mortality; (b) duration of hospitalization; (c) hemodynamic stability; (d) electrical stability; (e) left ventricular ejection fraction.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017062434621N1**  
Registration date: **2017-08-05, 1396/05/14**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-05, 1396/05/14

##### Registrant information

###### Name

Azadeh Mozayani Monfared

###### Name of organization / entity

Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3838 1731

###### Email address

a.mozayani@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-04-21, 1397/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of prophylactic intracoronary Adenosine infusion during primary percutaneous coronary intervention in Acute ST Elevation Myocardial infarction

##### Public title

Effect of intracoronary Adenosine infusion during primary

percutaneous coronary intervention in Acute Myocardial infarction

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: (a) ST elevation MI in ECG; (b) LAD and LCX lesion; (c) coronary lesion suitable for angioplasty; (d) TIMI flow 0-1. Exclusion criteria: (a) history of COPD or asthma; (b) patients who under treatment with dipyridamol; (c) Presentation with cardiogenic shock; (d) Patients who received fibrinolytic; (e) life expectancy less than 6 month; (f) stent thrombosis; (g) history of CABGs; (h) AV nodal block in first ECG; (I) TIMI flow 2-3 in angiography; (j) RCA lesion; (k) lack of patient satisfaction.

### **Age**

No age limit

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **104**

### **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**

Local Human Subject Review Board

##### **Street address**

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave, Hamadan

##### **City**

Hamadan

##### **Postal code**

6517838695

#### **Approval date**

2017-05-13, 1396/02/23

#### **Ethics committee reference number**

IR.UMSHA.REC.1396.133

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Acute myocardial infarction

#### **ICD-10 code**

I21

#### **ICD-10 code description**

Ischaemic heart diseases

## **Primary outcomes**

### 1

#### **Description**

ST elevation resolution

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

ECG

### 2

#### **Description**

TIMI flow

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Angioplasty

### 3

#### **Description**

level of CKMB and troponin

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Blood sample

## **Secondary outcomes**

### 1

#### **Description**

Inhospital mortality

#### **Timepoint**

After intervention

#### **Method of measurement**

check list

### 2

#### **Description**

duration of hospitalization

#### **Timepoint**

After intervention

#### **Method of measurement**

check list

### 3

**Description**

hemodynamic stability

**Timepoint**

After intervention

**Method of measurement**

check list

### 4

**Description**

electrical stability

**Timepoint**

After intervention

**Method of measurement**

ECG

### 5

**Description**

Left ventricular ejection fraction

**Timepoint**

After intervention

**Method of measurement**

Echocardiography

## Intervention groups

### 1

**Description**

Intervention group: Two separated doses of 40 microgram adenosine in 10 ml normal saline 0.9% intracoronary infusion during primary PCI on LAD or LCX.

**Category**

Prevention

### 2

**Description**

Control group: Two separated doses of Intracoronary 10 ml normal saline 0.9% infusion in left coronary system.

**Category**

Prevention

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Farshchian Heart Center

**Full name of responsible person**

Behshad Naghshtabrizi

**Street address**

Farshchian Heart Center, Shaheed Fahmideh Ave.

**City**

Hamadan

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

**Full name of responsible person**

Saeid Bashirian

**Street address**

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

**City**

Hamadan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vic-chancellor of Research and Technology, Hamadan 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**

Clinical Research Development Unit of Farshchian Heart Center, Department of Cardiology

**Full name of responsible person**

Manijeh Sajedi

**Position**

Resident of Cardiology

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

Shaheed Fahmideh Ave., Farshchian Heart Center

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**Phone**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Department of Cardiology, School of Medicine

**Full name of responsible person**

Behshad Naghshtabrizi

**Position**

MD, Associate Professor of Cardiology

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Department of Cardiology, School of Medicine

**Full name of responsible person**

Azadeh Mozayani Monfared

**Position**

Cardiologist

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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*