

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effect of intracoronary adenosine injection before stenting in emergency primary percutaneous coronary intervention for preventing no-reflow phenomenon in patients with ST elevation myocardial infarction

Protocol summary

Study aim

To determine the effect of intracoronary adenosine injection before stenting in emergency primary percutaneous coronary intervention for preventing no-reflow phenomenon in patients with ST-elevation myocardial infarction

Design

The patients were randomized into intervention and the control group. The intervention group received intracoronary adenosine and the control group received no drug or placebo.

Settings and conduct

Recruitment will be done in the emergency department of Imam Khomeini Hospital and the other steps of the study will be done in the catheterization laboratory of Imam Khomeini Hospital. None of the patients were aware of the allocated group.

Participants/Inclusion and exclusion criteria

Patients with acute STEMI who presented to the emergency department of Imam Khomeini Hospital (Tehran, Iran) and underwent primary PCI were enrolled. The inclusion criteria were the diagnosis of STEMI at the emergency department, having full criteria for primary PCI, TIMI flow grade = 0-1 in the coronary angiography, and giving consent to take part in our study. The exclusion criteria were a cardiogenic shock, complete AV block, severe renal failure (serum creatinine > 3 mg/dl) and need for emergent coronary bypass graft surgery.

Intervention groups

The intervention group received intracoronary adenosine (200 mcg bolus for right side coronary arteries and 400 mcg bolus for the left side coronary arteries) through the guiding catheter before stenting.

Main outcome variables

The primary end-point of the study was the occurrence of the no-reflow phenomenon that was defined as: TIMI flow grade<3 Myocardial blush grade<=2 TIMI frame count

<36 for left ascending coronary artery, <22 for the left circumflex artery and <20 for the right coronary artery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120516009768N6**

Registration date: **2019-07-21, 1398/04/30**

Registration timing: **retrospective**

Last update: **2019-07-21, 1398/04/30**

Update count: **0**

Registration date

2019-07-21, 1398/04/30

Registrant information

Name

Akbar Shafiee

Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-03-03, 1397/12/12
Actual recruitment end date
2019-03-21, 1398/01/01
Trial completion date
2019-09-01, 1398/06/10

Scientific title

Effect of intracoronary adenosine injection before stenting in emergency primary percutaneous coronary intervention for preventing no-reflow phenomenon in patients with ST elevation myocardial infarction

Public title

Effect of intracoronary adenosine injection before stenting in emergency primary percutaneous coronary intervention for preventing no-reflow phenomenon in patients with ST elevation myocardial infarction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of ST-elevation myocardial infarction based on electrocardiogram and laboratory test Consent for taking part in the study TIMI flow grade=0-1 in the coronary angiography Having the criteria for primary percutaneous coronary intervention

Exclusion criteria:

Cardiogenic shock Complete AV block Chronic Renal Failure (Serum creatinine >3 mg/dl) Need for emergency coronary artery bypass graft surgery

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **220**

Actual sample size reached: **228**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using an internet-based software that did simple randomization.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were unaware of their study group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Imam Khomeini Hospital

Street address

Gharib St

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.349

Health conditions studied

1

Description of health condition studied

ST segment elevation myocardial infarction

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

No reflow phenomenon is the failure of blood to reperfuse an ischemic area after revascularization

Timepoint

After stenting

Method of measurement

Based on the angiographic tools: TIMI flow grade, TIMI frame count & Myocardial blush grade

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Will receive intracoronary adenosine infusion (200 mcg bolus for right-side coronary arteries and 400 mcg bolus for the left-side coronary arteries) through the guiding catheter before stenting.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive no intervention and will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mohammad Sadeghian

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Imam Khoemini Hospital, Dr. Gharib st, Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Shafiee

Position

Research Associate

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Anonymous data will be analyzed and published as a research article

When the data will become available and for how long

Second half of 2019

To whom data/document is available

Researcher and clinicians at Tehran University of Medical Sciences

Under which criteria data/document could be used

For research purpose only and by indicating the source of data

From where data/document is obtainable

Dr. Mohammad Sadeghian, department of Cardiology, imam Khomeini Hospital. Email: msadeghian@sina.tums.ac.ir

What processes are involved for a request to access data/document

Sending a proposal

Comments