Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of Intracoronary Adenosine Injection on Outcomes of Primary Percutaneous Intervention in Patients with ST-segment Elevation Myocardial Infarction; A randomized controlled clinical trial

Protocol summary

Study aim

The aim of this study is to determine the impact of administering adenosine during coronary angioplasty on the clinical outcomes of primary angioplasty in patients with acute myocardial infarction with ST segment elevation who are referred to Heshmat Heart Hospital.

Design

Randomized, parallel-group, triple-blind, phase 3 clinical trial on 120 patients. In this study, consecutive patients with acute STEMI, willing to participate in the study, who meet the entry criteria and do not have the exit criteria, and of both sexes, who are PPCI, are randomly assigned to two groups using the random block method of 4. According to the sample size (N = 118, approximately 120), 30 random blocks will be generated through the Random Allocation software.

Settings and conduct

Heshmat Rasht Hospital

Participants/Inclusion and exclusion criteria

Patients with acute STEMI undergoing primary PCI. Inclusion criteria: diagnosis of STEMI in the emergency department, meeting criteria for primary PCI, TIMI flow 0-0-1 grade = coronary angiography, and informed consent. Exclusion criteria: cardiac shock, complete AV block, severe renal failure (serum creatinine > 3 mg/dL), need for emergency coronary artery bypass surgery, and history of coronary revascularization.

Intervention groups

Patients are included in the study based on daily visits in groups A (Adenosine injection) and group C (without adenosine injection/routine care with 5 cc of normal saline).

Main outcome variables

(Major adverse cardiac events) MACE, which in this study is a combination of cardiac death, non-fatal myocardial infarction, any re-angiogenesis and stroke, and are defined according to The Academic Research Consortium. (25) Measurement periods: during forty days after the intervention How to measure the variable: All patients will be followed up for MACE for 40 days, either through a clinic visit or through a telephone interview.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055645N6**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **prospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date

2023-06-07, 1402/03/17

Registrant information

Name

Fatemeh Baharvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 13 3361 8177

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Intracoronary Adenosine Injection on Outcomes of Primary Percutaneous Intervention in Patients with ST-segment Elevation Myocardial Infarction; A randomized controlled clinical trial

Public title

The Effect of Intracoronary Adenosine Injection on Outcomes of Primary Percutaneous Intervention in Patients with ST-segment Elevation Myocardial Infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of STEMI in the emergency department Having complete criteria for primary PCI TIMI flow grade= 0-0-1 Coronary angiography Informed consent

Exclusion criteria:

Cardiogenic shock Complete AV block Severe renal failure (serum creatinine> 3 mg/dL) Need for emergency coronary artery bypass surgery History of recurrent coronary artery disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, consecutive patients with acute STEMI, willing to participate in the study, who meet the inclusion criteria and do not have the exclusion criteria, and of both sexes, who are candidates for PPCI, are randomly assigned to two groups using the random block method of 4. According to the sample size (N = 118, approximately 120), 30 random blocks will be generated through the Random Allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study will be conducted as a triple-blind trial, and the control group will receive the normal saline volume injection just because of blinding purposes. After selecting the samples, neither the participants nor the physicians will have any knowledge about randomization and allocation process to the groups. The physicians will be given a pre-assigned coded number table and will enter the patients into the study according to their table numbers. The drug packages are completely identical in appearance, and both the patients and the study executor are unaware of their contents. Furthermore, data collection, patient assessment, and form completion will be performed by the study executor and their assistant who are also unaware of the drug package contents. In data analysis stage, analysis will be performed by both a consultant researcher and study executor who are also unaware of drug package contents, and only the patient group (group 1 or 2) for data analysis will be determined. Therefore, this is a triple-blind study where drug package contents are not known from patient entry to study completion, data collection, and information analysis.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan University of Medical Sciences

Street address

Namjoo

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.GUMS.REC.1402.108

Health conditions studied

1

Description of health condition studied

Acute transmural myocardial infarction of unspecified site

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description
(Major adverse cardiac events) MACE, which in this study is a combination of cardiac death, non-fatal myocardial infarction, any re-angiogenesis and stroke, and are defined according to The Academic Research Consortium.
Timepoint
Within forty days after the intervention
Method of measurement
All patients will be followed up for MACE for 40 days, either through clinic visits or telephone interviews

Secondary outcomes

1

Description
No-reflow phenomenon refers to the lack of blood flow after coronary artery reopening
Timepoint
before and immediately after primary angioplasty
Method of measurement
based on angiographic criteria such as TIMI flow grade and TIMI frame count

2

Description
ST-segment resolution (STR) is considered if the ST segment returns more than 70% to the isoelectric line 90 minutes after injection
Timepoint
before and 90 minutes after intervention
Method of measurement
Standard 12-lead ECG will be taken from all patients at hospital admission and 90 minutes after PPCI. The sum of ST segment elevation, 20ms after the J point in all leads will be recorded. After calculating the total increase in ST-segment elevation in leads representing the infarct location on the baseline ECG and at minute 90, STR will be expressed as a percentage by dividing the second number by the first number and subtracting it from 100

3

Description
left ventricular ejection fraction (LVEF) refers to how well the left ventricle pumps blood with each contraction
Timepoint
Before the intervention and 40 days after the intervention
Method of measurement
By a cardiologist with an echocardiography device using the Biplaine Simpson method, then the percentage of LVEF recovery will be calculated as the difference between the initial LVEF and 40 days later.

Intervention groups

1

Description
Intervention group: Adenosine injection
Category
Treatment - Drugs

2

Description
Control group: No adenosine injection/routine care with 5 cc of normal saline
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmat Heart Hospital
Full name of responsible person
Fatemeh Baharvand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Guilan University of Medical Sciences
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Parastar
City
Rasht
Province
Guilan
Postal code
41937-13111
Phone
+98 13 3334 6489
Email
riasat@gums.ac.ir
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
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Position
Assistant Professor of Interventional Cardiology
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data except personal information (name, contact number, file number) can be published.
When the data will become available and for how long
After publishing the results
To whom data/document is available
Available to service providers such as doctors and nurses.
Under which criteria data/document could be used
After obtaining permission from the project manager, the information will be usable.

From where data/document is obtainable

Project manager

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

By email to the project manager

Comments

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