Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative analysis of the effects of intracoronary injection nitroglycerin, warm saline , and adenosine prior to stenting; on post-stenting coronary blood flow improvement in patients presenting with acute myocardial infarction

Protocol summary

Study aim
Comparative analysis of the effects of intracoronary injection nitroglycerin, warm saline , and adenosine prior to stenting; on post-stenting coronary blood flow improvement in patients presenting with acute myocardial infarction

Design
A phase 4 randomized, single-blind, controlled, parallel-group clinical trial on 120 patients. Randomization will be performed using statistical software.

Settings and conduct
This clinical trial will include 120 patients with acute myocardial infarction at Shahid Madani Hospital who meet inclusion/exclusion criteria. Patients will be randomly allocated to four intervention groups. After stent implantation, coronary flow will be assessed by TIMI flow grade (0–3) as the primary outcome. Patients will be blinded to allocation, and informed consent will be obtained before enrollment.

Participants/Inclusion and exclusion criteria
Age between 18-80 years old chest pain candidate for primary Percutaneous coronary intervention (primary PCI) Angioplasty within 12 hours of the onset of chest pain symptoms ST elevation of at least 1 millimeter in two contiguous leads presence of acute Left Bundle Branch Block (LBBB) Systolic Blood Pressure≥90 mm-hg definite diagnosis of No-Reflow -Slow flow with Thrombolysis in Myocardial Infarction (TIMI) grade ≤2 on the first diagnostic injection diagnostic injection patients with an ejection fraction above 20%. ; presence of severe valve disease or congenital heart disease known allergic reaction to nitroglycerine or adenosine contraindication of aspirin or clopidogrel cardiomyopathy pericarditis pregnancy

Intervention groups
Group 1 (Control): No drug after wire, before stent. Group 2 (Warm saline): 20 ml saline at 37°C. Group 3 (Nitroglycerin): 100 µg intracoronary. Group 4 (Adenosine): 50 µg intracoronary.

Main outcome variables
coronary blood flow after stent implantation, measured by TIMI flow grade at the end of PCI.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250922067324N1**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **prospective**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date
2025-09-26, 1404/07/04

Registrant information

Name
Mohammad Rajabpour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3323 9434

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rajabpour45@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-04-19, 1405/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative analysis of the effects of intracoronary injection nitroglycerin, warm saline , and adenosine prior to stenting; on post-stenting coronary blood flow improvement in patients presenting with acute myocardial infarction

Public title

effects of nitroglycerin, warm saline , and adenosine on coronary blood flow improvement.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-80 years old chest pain candidate for primary Percutaneous coronary intervention (primary PCI) Angioplasty within 12 hours of the onset of the first chest pain symptoms presence of ST-segment elevation in two contiguous leads at least 1 millimeter presence of acute Left Bundle Branch Block (LBBB) SBP≥90 mm-hg definite diagnosis of No-Reflow -Slow flow with Thrombolysis in Myocardial Infarction (TIMI) grade ≤2 on the first diagnostic injection patients with an Ejection Fraction(EF) above 20%.

Exclusion criteria:

presence of severe valve disease or congenital heart disease known allergic reaction to nitroglycerine or adenosine contraindication of aspirin or clopidogrel cardiomyopathy pericarditis pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated to four groups using block randomization with a block size of 8 (randomization unit: each patient). The random sequence will be generated by an independent statistician using statistical software; all possible combinations of the four groups within blocks of 8 will be created and randomly ordered until the final sequence for 120 patients is obtained. The sequence will be kept in sequentially numbered, opaque, sealed envelopes, which will be opened at the time of patient enrollment

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will not be informed about the specific treatment group to which they are assigned; however, informed consent will be obtained prior to enrollment, and they will be aware that allocation is random to one of four treatment groups. The random sequence will be generated by an independent statistician and kept in sequentially numbered, opaque, sealed envelopes. At patient enrollment, the corresponding envelope will be opened, and the assigned intervention will be prepared and administered. The clinical team will be instructed not to disclose allocation to the patient, and all procedures will be documented. Thus, the study will be conducted in a single-blind manner.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Kilometer 4, Khorramabad–Borujerd Road, Khorramabad, Lorestan Province

City

Khorramabad

Province

Lorestan

Postal code

6814993165

Approval date

2025-06-07, 1404/03/17

Ethics committee reference number

IR.LUMS.REC.1404.120

Health conditions studied

1

Description of health condition studied

Acute Myocardial Infarction

ICD-10 code

121

ICD-10 code description

myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset

Primary outcomes

1

Description
coronary blood flow after stent implantation, assessed by Thrombolysis in Myocardial Infarction (TIMI) score
Timepoint
Before and immediately after stent implantation
Method of measurement
TIMI Flow grade

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Before and after stent implantation
Method of measurement
Manual sphygmomanometer

2

Description
Left Ventricular Ejection Fraction
Timepoint
Before and after stent implantation
Method of measurement
Echocardiography

Intervention groups

1

Description
Control group: After wire passage, with or without balloon, and before stent implantation, no drug will be administered.
Category
Treatment - Other

2

Description
Intervention group: First Intervention group: After wire passage, with or without balloon, and before stent implantation, 20 ml of normal saline warmed to 37°C will be injected via the guiding catheter.
Category
Treatment - Drugs

3

Description
Intervention group: Second Intervention group: After wire passage, with or without balloon, and before stent implantation, 100 µg of nitroglycerin will be administered intracoronary via the guiding catheter.
Category
Treatment - Drugs

4

Description
Intervention group: Third Intervention group: After wire passage, with or without balloon, and before stent implantation, 50 µg of adenosine will be administered intracoronary via the guiding catheter.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani hospital
Full name of responsible person
Amir Shakarami
Street address
Shahid Madani Cardiovascular Specialty Hospital, Kheirabad Street, Shaghayegh, Khorramabad, Lorestan province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Amir Shakarami
Street address
Lorestan University of Medical Sciences, Kilometer 4, Khorramabad–Borujerd Road, Khorramabad, Lorestan Province
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Shakarami.amir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Amir shakarami
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Mahya building, golshan2 alley, pasdaran street, khorramabad city, lorestan province
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Person responsible for updating data

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Street address
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6814989676
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Shakarami.amir@yahoo.com

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
Yes - There is a plan to make this available
Title and more details about the data/document
Individual participant data, after de-identification, limited to the main outcome variables (such as TIMI flow grade), will be available. Data will be shared upon reasonable request from qualified researchers and after approval by the Ethics Committee. No confidential or identifying information of patients will be released.
When the data will become available and for how long
Access to de-identified data will be available starting 6 months after publication of the study results and will continue for 3 years.

To whom data/document is available

De-identified data will be available only to researchers affiliated with academic institutions or recognized scientific centers. Access will be granted upon formal request and approval by the Ethics Committee.

Under which criteria data/document could be used

De-identified data will be used solely for research and academic purposes; commercial or unrelated use is not permitted. Analyses must be limited to scientific topics related to cardiovascular diseases. Applicants are required to submit a research proposal, and access will be granted only after approval by the Ethics Committee.

From where data/document is obtainable

For access to the study data, applicants may contact the principal investigator: Name: Dr. Amir Shakeri Position: Principal Investigator Email: Shakarami.amir@yahoo.com Phone: 0098 66 633120155 Address: Lorestan University of Medical Sciences, Km 4, Khorramabad-Borujerd Road, Khorramabad, Lorestan, Iran

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

Applicants requesting access to the data should follow these steps: 1. Submit a formal request to the principal investigator via email or mail. 2. Provide a short research proposal including objectives, methods, and planned analyses. 3. The proposal will be reviewed and approved by the Ethics Committee. 4. Upon approval, de-identified data will be provided in a secure format along with usage instructions. The total process usually takes 4 to 6 weeks from the date of request to data delivery.

Comments