Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Study of the effect of Intra-coronary morphine vs placebo in the treatment of acute ST-segment elevation myocardial infarction

Protocol summary

Study aim
Evaluation of cardio protective effects of intra coronary morphine in patients with STEMI referred for PPCI.

Design
A clinical trial with the control group, double-blind, randomized, phase 3 on 110 patients. For randomization, a random sequence is used by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com).

Settings and conduct
Patients referred to Shahid Beheshti Hospital of Qom with acute myocardial infarction are divided into two groups using block randomization method. The intervention group underwent percutaneous primary coronary intervention with the drug morphine (5 mg in 3 ml of saline) and the control group received a placebo (3 ml of normal saline). Transthoracic echocardiography was performed on days 1 and 6 and the output The left ventricle will be calculated using the two-way Simpson method. Troponin T level (measured every 12 hours during the first 24 hours and then every 12 hours for the next 48 hours), LVEF measured by echocardiography with the same operator on days 1 and 6 and the clinical result will be evaluated after 3 months. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion: age older than 18 years; Acute myocardial infarction with ST segment elevation Exclusion: allergy to morphine; coronary artery bypass grafting; resuscitated cardiac arrest; mechanical ventilation upon arrival; Morphine injection in the emergency room; right ventricular stroke; serious liver failure and Cardiac arrhythmia

Intervention groups
The intervention group underwent percutaneous primary coronary intervention with morphine drug (5 mg in 3 ml of saline) and the control group received placebo (3 ml of normal saline).

Main outcome variables
Coronary Reperfusion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220814055685N1**
Registration date: **2022-12-10, 1401/09/19**
Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**
Update count: **0**

Registration date
2022-12-10, 1401/09/19

Registrant information

Name
seyed fakhrodin hejazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3612 2000

Email address
sf-hejazi@muq.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of Intra-coronary morphine vs placebo in the treatment of acute ST-segment elevation myocardial infarction

Public title
Effect of intra coronary morphine in STEMI

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years Acute myocardial infarction with STEMI patients

Exclusion criteria:
Known allergy to morphine hydrochloride Patients with coronary artery bypass grafting Patients with cardiac arrest are resuscitated Mechanical ventilation on arrival Morphine injection in the emergency room Patients with right ventricular stroke Serious failure of liver cells Any cardiac arrythmia

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com).

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the clinical caregiver, and outcome assessor were blinded to the group allocation. In order to hide the concealment from random allocation, we use the method used to implement a random sequence on the participants in the study, such that before the allocation of the individual, the assigned group does not specify. by using non - transparent sealed envelopes with a random sequence in (Sequentially numbered, sealed, opaque envelopes) In this method each of the random created on a card is placed in the mail packet, respectively .in order to maintain a random sequence, it is performed on the outer surface of .finally, the envelope of the envelope packets is glued inside the box .at the beginning of registration of the participants, according to the order of eligible participants to study, one of the mail envelopes is unfolded, and the assigned group of the participants is revealed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences

Street address
Shahid Lavasani St

City
Qom

Province
Ghoum

Postal code
3713649373

Approval date
2022-06-12, 1401/03/22

Ethics committee reference number
IR.MUQ.REC.1401.070

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction with ST elevation

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Coronary reperfusion

Timepoint
One and Six Day after the intervention

Method of measurement
Trans thoracic echocardiography

Secondary outcomes

1

Description
Cardiac enzyme(troponin)

Timepoint
Every 12 hours during the first 24 hours and then every 12 hours for the next 48 hours
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: One dose of morphine sulfate hydrochloride with a dose of 5 mg with a single administration slowly over a period of one to two minutes at the beginning of primary PCI inside the coronary arteries.
Category
Treatment - Drugs

2

Description
Control group: Patients undergoing PPCI receive 3 cc of normal saline intracoronary after receiving routine treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Seyed Fakhreddin Hejazi
Street address
Shahid Beheshti Hospital - Shahid Beheshti Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
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No. 83, Safashehr St., Shahid Lotfi Niaser- Shahid Lotfi Niaser Alley, Safashehr Street
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Seyed Fakhreddin Hejazi
Position
Associate Professor
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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
No - There is not a plan to make this available

Title and more details about the data/document
All data can be shared after people have not been identified

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Use of meta-analysis

From where data/document is obtainable
To the responsible author whose details were given and it is also clear in the relevant articles.

What processes are involved for a request to access data/document
Correspondence with the responsible author

Comments