

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 arrhythmia

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

Ghous

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

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2000

Email

bmc@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Dr. Ali Reza Koohpaei

Street address

No. 83, Safashehr St., Shahid Lotfi Niaser- Shahid Lotfi Niaser Alley, Safashehr Street

City

Qom

Province

Ghous

Postal code

3716993456

Phone

+98 25 3285 2720

Email

research@mail.muq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Seyed Fakhreddin Hejazi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Shahid Beheshti Blv

City

Qom

Province

Ghous

Postal code

3719964797

Phone

+98 25 3612 2000

Email

sf-hejazi@muq.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Ali Abdollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Shahid Beheshti Blv
City
Qom
Province
Ghoum
Postal code
3719964797
Phone
+98 25 3612 2000
Email
aliabdollahi11@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
Ali Abdollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Shahid Beheshti Blv
City
Qom
Province
Ghoum
Postal code

3719964797

Phone
+98 25 3612 2000

Email
aliabdollahi11@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

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