

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of morphine administration on serum CKMB level, ST segment depression and TIMI effect in patients with first acute anterior myocardial infarction who underwent primary coronary angioplasty.

Protocol summary

Study aim

-the effect of morphine on serum CKMB level after primary angioplasty in patients with first acute myocardial infarction -the effect of morphine on ST-segment depression after primary angioplasty in patients with first acute myocardial infarction -the effect of morphine on the final coronary TIMI flow of patients with acute myocardial infarction who undergo primary angioplasty

Design

A clinical trial with a control group, double-blind, randomized and phase 2 on 200 patients, and one patient is placed in the control and intervention group

Settings and conduct

Patients with acute anterior myocardial infarction were referred to Shahid Madani Hospital in Tabriz for primary angioplasty divided into two control and intervention groups, and the intervention group received 3 mg of intravenous morphine injection and one milligram of morphine are placed intracoronarily, but the control group will receive distilled water as a placebo. Patients and personnel who inject morphine and those who take blood samples and electrocardiograms are blinded. Blood samples are sent for CKMB levels.

Participants/Inclusion and exclusion criteria

inclusion: typical cardiac chest pain at least 20 minutes / ST segment elevation of at least 1 mm / the first acute myocardial infarction of the patient / myocardial infarction in the last 6 hours / initial TIMI score is 0 or 1 / no morphine injection in the emergency room. exclusion: receiving fibrinolytic / receiving cardiac electric shock / patient resuscitation / patient intubation / having VT or VF arrhythmia / history of CABG / complete heart block / respiratory failure / history of liver cirrhosis / primary TIMI 2 and or more will be excluded from the study.

Intervention groups

patients with acute anterior myocardial infarction who have been referred cath lab for primary angioplasty

Main outcome variables

MORPHIN;ST SEGMENT RESOLUTION;CORONARY TIMI FLOW;CKMB LEVEL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230102057018N1**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Tohid YAHYAPOOR Talatapeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of morphine administration on serum CKMB level, ST segment depression and TIMI effect in patients with first acute anterior myocardial infarction who underwent primary coronary angioplasty.

Public title

Effect of morphin in prognose of Anterior MI

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Typical cardiac chest pain lasting at least 20 minutes ST segment elevation of at least 1 mm repeated in two consecutive leads Q wave not seen with ST segment elevation patient's first acute anterior myocardial infarction A heart attack has occurred in the last 6 hours initial TIMI score is 0 or 1 no morphine injection in the emergency room or before

Exclusion criteria:

receiving fibrinolytic receiving cardiac electric shock resuscitating the patient being intubated having VT or VF arrhythmia history of CABG complete heart block respiratory failure history of liver cirrhosis early TIMI flow 2 or more

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization(Random allocation rule)/Random allocation software(SAS)/In order to hide, the method of Numbered drug containers will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

- Apart from knowing the type of study and participation in the study and possible complications, the participant is completely blinded to which group he is in and what the results of the data are like. - The health personnel have no knowledge of the type and process of the study and

only follow the orders - Those responsible for data collection and those who evaluate the outcome are completely blinded to the study process

Placebo

Used

Assignment

Parallel

Other design features

In this study, the dose of morphine received was different compared to similar studies, and also three cases of TIMI FLOW, ST and CKMB levels will be evaluated together for the first time.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Azadi St., Golbad St., University St.

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Tabriz

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East Azarbaijan

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5166615573

Approval date

2022-12-05, 1401/09/14

Ethics committee reference number

IR.TBZMED.REC.1401.802

Health conditions studied**1****Description of health condition studied**

Acute Anterior ST Elevatiom Myocardial Infarction

ICD-10 code

I21.0

ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

Primary outcomes**1****Description**

coronary timi flow

Timepoint

in angiographic last view

Method of measurement

According to the international definition of coronary Timi Flow

Secondary outcomes

1

Description

The degree of ST segment depression in the patient's ECG

Timepoint

90 minutes after the patient enters the CCU

Method of measurement

Obtaining an ECG by the patient's nurse and reading it by a cardiologist

Intervention groups

1

Description

Intervention group: For this group, morphine sulfate is injected in the lab coat and on the angiography bed with a dose of 1 mg intracoronary and 3 mg intravenous. 3 mg of intravenous morphine diluted with 5 cc of distilled water and 1 mg of intracoronary morphine diluted with 5 cc of distilled water and injected only once at the beginning of angioplasty in the doses described. 90 minutes after angioplasty, an electrocardiogram was taken in ccu and compared with the initial tape in terms of ST segment loss. During admission to the ccu and at an interval of 8 hours, blood is taken from the patient up to 3 times and sent to the laboratory to evaluate the level of ckmb. The angiography films are given a TIMI FLOW score according to the final TIMI flow.

Category

Treatment - Drugs

2

Description

Control group: Control group: This group does not receive any morphine and on the angiography bed, only 5 cc of distilled water is injected intracoronary and 5 cc of distilled water intravenously. 90 minutes after angioplasty in the ccu, an ECG is taken from the patients and it is compared with the initial tape in terms of ST segment loss. When entering the ccu and at an interval of 8 hours, the patient's blood is taken 3 times and sent to the laboratory to evaluate the ckmb level. The angiography films will be awarded according to the final TIMI flow by the project manager and the points corresponding to TIMI FLOW will be awarded to them. The implementation of the plan is evaluated and reviewed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Shahid Madani Heart and Vascular Specialist

Hospital

Full name of responsible person

Tohid Yahyapoor Talatapeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Assistant of Tabriz University of Medical Sciences

Full name of responsible person

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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

Research Assistant of Tabriz 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

Research Assistant of Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahaby

Position

Assistant Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available