

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The role of intravenous Acetaminophen versus intravenous Morphine sulfate in pain management and improvement of cardiac function in post acute MI patients who admitted to Hamadan Ekbatan Hospital

Protocol summary

Summary

Relieve pain and anxiety in patients who have suffered a myocardial infarction in the course of treatment is very important as it prevents the development of myocardial ischemia. Choose a drug that is safe and always available and can be easily used, have been considered by several studies. Morphine is a drug that is not easy to access and has limited its use in cases of hypotension, lung disease, diminish mental alertness ... so replace it with a drug such as acetaminophen, which is readily available and proven analgesic effect. Could be an important therapeutic strategy. Objectives: The purpose of this study is to investigate the role of acetaminophen in pain management and cardiac function in patients with myocardial infarction. Design: In this clinical trial study, seventy patients (males and females) in the age range of 40-80 years who admitted to Hamedan Ekbatan hospital with diagnosis of myocardial infarction will investigate. The patients divided into 2 groups: 35 in control group, 35 in test group. Setting and conduct: Test group will receive 4 doses of intravenous acetaminophen 1 gram intravenously every 6 hours, dissolved in 100 mL of normal saline. Control group will receive intravenous Morphine sulfate (3 mg every 6 hours for 4 times) for pain control. Visual analogue scale (VAS), blood pressure and heart rate will be measured at 0, 0.5, 1, 2, 4, 6, 12, 18 and 24 hours post admission. All patients underwent echocardiography 3 days and 6 weeks after MI. Participant including major eligibility criteria: Including criteria to study: age range between 40-80 years old patients: who admitted to Hamedan Ekbatan hospital with diagnosis of myocardial infarction by using signs and ECG for the detection. Exclusion criteria to study: systolic blood pressure less than 100 mm Hg or greater than 200 mm Hg; diastolic blood pressure below 60 mm Hg; history of previous myocardial infarction; fibrinolytic therapy or revascularization; hepatic and renal disease;

addiction to Opium consumption; VAS (Visual Analogue Scale) greater than 3; loss of consciousness. Intervention: Test group will receive 4 doses of intravenous acetaminophen 1 gram intravenously every 6 hours, dissolved in 100 mL of normal saline. Control group will receive intravenous Morphine sulfate (3 mg every 6 hours for 4 times) for pain control. Main outcome measures (variables): Investigation of below variables comparison with control group 1. Visual analogue scale (VAS) 2. blood pressure 3. heart rate (at 0, 0.5, 1, 2, 4, 6, 12, 18 and 24 hours post admission) 4. left ventricular ejection fraction 5. regional wall motion abnormalities (by means of echocardiography 3 days and 6 weeks after MI.)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405133954N7**

Registration date: **2015-04-26, 1394/02/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-26, 1394/02/06

Registrant information

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Mohammad Hossein Bakhshaei

Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2014-09-23, 1393/07/01

Expected recruitment end date
2015-08-31, 1394/06/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The role of intravenous Acetaminophen versus intravenous Morphine sulfate in pain management and improvement of cardiac function in post acute MI patients who admitted to Hamadan Ekbatan Hospital

Public title
Intravenous Acetaminophen analgesic effects and improvement of cardiac function in myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 40-80 years old patients : who admitted to Hamedan Ekbatan hospital with using signs and ECG for the detection of myocardial infarction .
Exclusion criteria: systolic blood pressure less than 100 mm Hg or greater than 200 mm Hg : diastolic blood pressure below 60 mm Hg : history of previous myocardial infarction : fibrinolytic therapy or revascularization : hepatic and renal disease : addiction to Opium consumption : VAS(Visual Analogue Scale) greater than 3 : loss of consciousness.

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamehan University of Medical Sciences

Street address

University of Medical Sciences,Shahid Fahmideh boulevard

City

Hamedan

Postal code

Approval date

2014-06-25, 1393/04/04

Ethics committee reference number

16/35/9/1544/پ

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I 21 , I 2

ICD-10 code description

Acute myocardial infarction Incl.:myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onsetExcl.:certain current complications following acute myocardial infarction (I23.-) myocardial infarction:•old (I25.

2

Description of health condition studied

Analgesia

ICD-10 code

R00 , R01

ICD-10 code description

Cardiac murmurs and other cardiac sounds :
Abnormalities of heart beat : Pain in throat and chest :
Other symptoms and signs involving the circulatory and respiratory systems :

Primary outcomes

1

Description

myocardial infarction pain

Timepoint

0,0.5,1,2,4,6,12,18,24 hours after myocardial infarction

Method of measurement

Visual Analogue Scale

2

Description

Heart rate

Timepoint

0,0.5,1,2,4,6,12,18,24 hours after myocardial infarction

Method of measurement

Holter monitoring

3

Description

Arterial blood pressure

Timepoint

0,0.5,1,2,4,6,12,18,24 hours after myocardial infarction

Method of measurement

Holter monitoring

Secondary outcomes

1

Description

cardiac function

Timepoint

3rd and 42th days after myocardial infarction

Method of measurement

by Echocardiography

Intervention groups

1

Description

All patients will receive initial treatment of myocardial infarction in arrival emergency department. The treatment consists of oxygen by nasal, oral aspirin 325 mg, sublingual nitrate for up to 3 doses and initial dose of intravenous morphine 3 mg. The intervention group will receive 4 doses of acetaminophen 1 gram intravenously every 6 hours, dissolved in 100 mL of normal saline. Methods: 70 pack of dark colors written on them from 1 to 70 are randomly divided into two groups of 35. Inside each envelope is a card on which the letters A (acetaminophen treatment group) or the letter B (morphine treatment group) is written. The letter A or B can be placed inside the envelope are determined using a random numbers table. The first patient to be admitted, we're open Envelope 1, and patients indicates that the card is inserted into envelopes. Similarly, during the study, for each patient who is eligible for inclusion special envelopes will be opened by the numbers and them placed in the specified group. Pain score using Visual Analogue Scale for 0, 0.5, 1, 2, 4, 6, 12, 18 and 24 hours after MI is measured. Also in 0, 0.5, 1, 2, 4, 6, 12, 18 and 24 hours post-MI patients' blood pressure and heart rate will be measured. All patients underwent echocardiography 3 days and 6 weeks after MI then ischemic complications involving Hypokinesia, Akinesia and Dyskinesia and Ejection Fraction will be measure by Simpson technique.

Category

Treatment - Drugs

2

Description

In the control group if there is pain, will prescribe Morphine Sulfate 3 mg IV every 6 hours. Pain score using Visual Analogue Scale for 0.5, 1, 2, 4, 6, 12, 18 and 24 hours after MI is measured. Also in 0.5, 1, 2, 4, 6, 12, 18 and 24 hours post-MI patients' blood pressure and heart rate will be measured. All patients underwent echocardiography 3 days and 6 weeks after MI then ischemic complications involving Hypokinesia, Akinesia and Dyskinesia and Ejection Fraction will be measure by Simpson technique.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Heart center

Full name of responsible person

DR.B.Roozbahani MD Cardiology resident/DR.M.Malek poor MD Anesthesiology resident

Street address

Ekbatan Hospital Complex, St. Taleghani, Jahad Square

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Hamehan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

University of Medical Sciences, Shahid Fahmideh boulevard

City

Hamedan

Grant name

ندارد

Grant code / Reference number

not exist

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

Yes

Title of funding source

Vice chancellor for research Hamehan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty