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 recive intravenus Morphine sulfate (3 mg every 6 hours for 4 time)for pain control.Vsiual analogue scale(VAS) ,blood pressur and heart rate will be measure 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 recive intravenus Morphine sulfate (3 mg every 6 hours for 4 time)for pain control. Main outcome measures (variables): Investigation of below variables comparison with control group 1. Vsiual analogue scale(VAS) 2. blood pressur 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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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 Echocardiograghy

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 for0, 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
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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

Contact

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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