Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of morphine and morphine plus Apotel on pain relief, hemodynamic status and drug side effects In patients with acute myocardial infarction

Protocol summary

Study aim

Comparative study of the effect of morphine and morphine plus Apotel on pain relief, hemodynamic status and drug side effects In patients with acute myocardial infarction

Design

Clinical trial with control group, with parallel groups, randomized, phase 2-3 on 60 patients. Excel software rand function was used for randomization

Settings and conduct

Sixty patients with acute myocardial infarction referred to the emergency department of Al-Zahra Hospital in Isfahan, who met the inclusion and exclusion criteria, were randomly assigned to morphine and apoptil with morphine in groups of 30 and after full explanation and informed written consent, in Upon admission to the emergency department, they underwent standard monitoring including electrocardiography (ECG), invasive blood pressure (IBP), heart rate (HR), and arterial blood oxygen percentage (SPO2). After drug injection, pain intensity, hemodynamic parameters and drug side effects were monitored.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with chest pain and ECG changes indicating acute myocardial infarction or elevated ST segment, Age 20 to 80 years; Patient consent. Exclusion Criteria:Contraindications to taking Apotel and Morphine (severe diarrhea, pseudomembranous choline, acute respiratory failure, drug sensitivity, liver disease); Drug addiction

Intervention groups

Two treatment groups of 30 people including one group of morphine alone (control group) and one group of morphine with apotel were examined. In the first group (morphine alone) 5 mg of morphine in 10 minutes and in the second group (morphine-apotol) In addition to 5 mg of morphine, 1 g of apotel was infused over 30 minutes.

Main outcome variables

Pain intensity, systolic, diastolic blood pressure, mean arterial pressure, heart rate, blood oxygen saturation ,drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220119053760N1**
Registration date: **2022-02-13, 1400/11/24**
Registration timing: **retrospective**

Last update: **2022-02-13, 1400/11/24**
Update count: **0**

Registration date

2022-02-13, 1400/11/24

Registrant information

Name

Neda Abrishami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of morphine and morphine plus Apotel on pain relief, hemodynamic status and drug side effects In patients with acute myocardial infarction

Public title

Effect of morphine and morphine plus apotel on pain status, hemodynamic parameters and drug side effects in patients with acute myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chest pain and ECG changes indicating acute myocardial infarction or elevated ST segment, Age between 20 up to 80 years Patient consent

Exclusion criteria:

Contraindications to taking Apotel and Morphine (severe diarrhea, pseudomembranous choline, acute respiratory failure, drug sensitivity, liver disease) Drug addiction

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sixty patients with acute myocardial infarction were selected in easy manner at Al-Zahra Hospital in Isfahan and then, using Random Allocation software by simple random sampling method, patients were assigned to randomized groups of morphine and Apotel, respectively.

Blinding (investigator's opinion)

Not 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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences , Hezar Jerib St.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2018-07-11, 1397/04/20

Ethics committee reference number

1397.075.IR.MUI.MED.REC

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I23.8

ICD-10 code description

Other current complications following acute myocardial infarction

Primary outcomes

1

Description

Intensity of pain

Timepoint

Times: zero (basal), 15 minutes later, 30 minutes later, 45 minutes later, 60 minutes after injection

Method of measurement

The Visual Analogue Scale (VAS) was reported from zero (painless) to ten (maximum pain experienced).

2

Description

blood pressure

Timepoint

Times: zero (basal), 15 minutes later, 30 minutes later, 45 minutes later, 60 minutes after injection

Method of measurement

Mercury blood pressure monitor in millimeters of mercury

3

Description

Heart rate

Timepoint

Times: zero (basal), 15 minutes later, 30 minutes later, 45 minutes later, 60 minutes after injection

Method of measurement

Tethoscope counts heart rate (in minutes)

4

Description
Blood oxygen saturation percentage
Timepoint
Times: zero (basal), 15 minutes later, 30 minutes later, 45 minutes later, 60 minutes after injection
Method of measurement
Pulse oximeter

5

Description
drug side effects
Timepoint
Times: 15 minutes later, 30 minutes later, 45 minutes later, 60 minutes after injection
Method of measurement
Observe the patient's condition and ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 5 mg of morphine (manufactured by Darupakhsh Pharmaceutical Company in 10 mg ampoules with a volume of 1 ml) was diluted in 10 cc of distilled water and identified and used as a morphine solution and infused over a period of ten minutes. .
Category
Treatment - Drugs

2

Description
Intervention group: 1 g of Apotel (manufactured by Elixir Pharmaceutical Company in 1 g ampoules in 6.7 ml) was dissolved in 100 cc of normal saline by an emergency nurse, as a solution of Apotel and 5 mg of morphine (manufactured by Darupakhsh Pharmaceutical Company in 10 mg ampoules with a volume of 1 ml) were diluted in 10 cc of distilled water and identified and used as a morphine solution. Then morphine solution was infused for 10 minutes and apotol solution for 30 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Al-Zahra Hospital
Full name of responsible person
Dr. Mehrdad Esmailian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Mehrdad Esmailian

Position
Associate Professor of Emergency Medicine
Latest degree
Specialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
The data can be shared 6 months after the article is published and after identifying individuals.
When the data will become available and for how long
The data can be shared 6 months after the article is published and after identifying individuals.
To whom data/document is available
Doctors, specialists, nurses
Under which criteria data/document could be used
Comparison of new treatments
From where data/document is obtainable
Send email to n.abrishamy@gmail.com
What processes are involved for a request to access data/document
Send email to n.abrishamy@gmail.com
Comments