

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 apotel 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 colitis, 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-apotel) 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

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Name of organization / entity

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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
 Isfahan
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 apotel 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

Street address

Al-Zahra Hospital, Sofe Boulevard

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8174675731

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n.abrishamy@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash Dastjerdi

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Vice Chancellor for Research and Technology,
Building No. 4, Isfahan University of Medical Sciences
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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

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Position

Associate Professor of Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Student

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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