Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Analgesic effects of morphine suppository versus intravenous morphine in patients with extremity bone fracture: A placebo-controlled double-blind randomized clinical trial

Protocol summary

Summary

Objectives: Pain management is one of the major tasks of any emergency department. Finding a way to better control of pain can result in decreasing staff workload and increasing patient's satisfaction. Design:This is a double blind randomized placebo controlled clinical trial. setting:This study will be conducted patients with acute extremity fracture with age between 18-70 referred to our emergency departments.Patients with recent use of opiate; patients with severe liver, renal,lung disease; patients with sensitivity to morphine will be excluded.They will divided randomly into two group. First group will receive intravenous morphine 5 mg with placebo suppository and second group will receive 5cc Distilled water with suppository morphine.Then the patients will be examined from the view point of pain score in 0,15,60 minutes and after1,3,6,12,18,24 hours and need foe rescue analgesia and side effects. Assessment of pain will be done with Visual analogue scale (VAS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505218104N12**
Registration date: **2017-08-20, 1396/05/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Mohammad Amin Zare

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research, Iran University of Medical Sciences

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effects of morphine suppository versus intravenous morphine in patients with extremity bone fracture: A placebo-controlled double-blind randomized clinical trial

Public title

Acute pain control with morphine suppository

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: trauma patients with acute extremity fracture between 18 and 70 years old who have moderate to severe pain according to their visual

analogue scale (VAS) score (score equal or higher than 5 of 10) Exclusion Criteria: known opioid allergy, a history of current/past drug abuse, other concurrent causes of pain (including trauma to other site), history of any chronic diseases (like respiratory, renal, hepatic, or heart failure), any conditions impairing the patient's cooperation and participation in study (including altered consciousness, mental disorders and language barrier), pregnant and breastfeeding women and patients who had received analgesics 24 hours before admission

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **224**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
multi-center

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemmat and Sheikh Fazlollah highways cross

City
Tehran

Postal code
14457

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
IR.IUMS.REC.1394.9211307035

Health conditions studied

1

Description of health condition studied
Pain in extrimity fracture

ICD-10 code
XIX

ICD-10 code description
Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description
Severity of pain

Timepoint
0.30.60 minutes and 1,3,6,12,18,24 hour

Method of measurement
numerical criteria on the base of VAS score

Secondary outcomes

1

Description
Apnea,decreased Oxygen suturation, decreased level of consciousness, decreased blood pressure, nausea and vomiting

Timepoint
0-30-60 minutes and 1,3,6,12,18,24 hour

Method of measurement
Checking the patients respiratory rate, Oxygen saturation on pulse oximetry, checking blood pressure and asking about nausea and vomiting

Intervention groups

1

Description
Control group will receive intravenous morphine 5 mg and placebo suppository .

Category
Treatment - Drugs

2

Description
Case group will receive 10 mg suppository morphine and 5 ml of intravenous distilled water.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram hospital

Full name of responsible person
Mohammad Amin Zare

Street address

Niyayesh St, Sattarkhan Ave

City

Tehran

2

Recruitment center

Name of recruitment center

Haft-e-tir hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Shahre Rey-Shahid Radjayi Blvd.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research of Iran University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Eftekhar

Street address

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research of Iran 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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hoda Taghipour

Position

Resident of Emergency Medicine

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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