

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 in 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 be divided randomly into two groups. 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 after 1, 3, 6, 12, 18, 24 hours and need for 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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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 saturation, 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
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2

Recruitment center

Name of recruitment center
Haft-e-tir hospital
Full name of responsible person
Mohammad Amin Zare
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Shahre Rey-Shahid Radjayi Blvd.
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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 Eftekhari
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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

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

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Person responsible for updating data

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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