Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison analgesia effect of morphine and morphine plus low dose promethazine in opium dependent trauma patients

Protocol summary

Summary

Objectives: Comparing the analgesia effect of morphine and morphine plus low dose promethazine in opium dependent trauma patients Design: This double blind clinical trial, will be done in the emergency department of Rasoul Akram, Sina and Hafte Tir hospitals. The population of study is included in patients suffering opium addiction, who are admitted suffering severe pain(VAS≥6) due to upper or lower extremity fracture, requiring analgesia. Setting and conduct: All the patients who are recruited according to the inclusion and exclusion criteria, will fill in the informed consent form including complete information about the research progress, and all the patients who will have satisfaction to recruit in the study, will be the principle group of study. First of all, the researcher will fill out a form including data about demographic and any history of drug hypersensitivity, duration of substance abuse and type of substance, and than evaluated the severity of pain administering the Visual Analogue Scale(VAS). Before administering any drug, using randomization method, the patient will be placed in one of two groups. Following, the Pain Score will be reevaluated using the VAS at 10, 30, 60, 90, 120 and 180 minutes after and will be documented. The researcher will calculate and document the sedation score. Vital signs such as systolic and diastolic blood pressure, pulse rate, pulse oximetry, respiratory rate before drug and during administration in regular intervals will be evaluated. Statistical analysis in this study will be done after data gathering in SPSS software, T test will be used to compare the scores in two groups, and multivariate tests such as regression will be used to convert the effect of confounding factors in two groups. Inclusion Criteria: Age more than 18 years old; dependency to opium; fracture in upper or lower extremity; GCS=15; VAS≥6 ; ability to talk; stable hemodynamic. Exclusion Criteria: Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy with analgesic drugs; sensitivity to morphine or promethazine; unable to understand the VAS concept; pregnancy; necessity to nerve block; unwilling to take part in the intervention; refuse to continue the intervention; major trauma which is life threatening or causing defects; any history of chronic liver; kidney; lung; cardiac disease. Intervention: For the patients in group one, 0.1 mg/kg morphine as placebo and for the patients in the second group, 12.5 mg intravenous promethazine plus the same dose of morphine in the first group will be administered. Main Outcome: Changes in pain severity

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040717174N1**
Registration date: **2014-08-15, 1393/05/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

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Name of organization / entity
Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical

Sciences

Expected recruitment start date
2013-03-20, 1391/12/30
Expected recruitment end date
2014-03-20, 1392/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison analgesia effect of morphine and morphine plus low dose promethazine in opium dependent trauma patients

Public title
Pain control in opium dependent traumatic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Age more than 18 years old; dependency to opium; fracture in upper or lower extremity; GCS=15; VAS≥6 ; ability to talk; stable hemodynamic. Exclusion Criteria: Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy with analgesic drugs; sensitivity to morphine or promethazine; unable to understand the VAS concept; pregnancy; necessity to nerve block; unwilling to take part in the intervention; refuse to continue the intervention; major trauma which is life threatening or causing defects; any history of chronic liver; kidney; lung; cardiac disease
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Ghods street, Keshavarz blvd
City
Tehran
Postal code
Approval date
2013-05-25, 1392/03/04
Ethics committee reference number
130/342/92/د

Health conditions studied

1

Description of health condition studied
Extremity Trauma
ICD-10 code
XIII
ICD-10 code description
musculoskeletal system and connective tissue diseases

Primary outcomes

1

Description
Pain Severity
Timepoint
0, 10, 30, 60, 90 and 120 minutes after treatment
Method of measurement
Administration of Visual Analogue Scale and asking the patient to determine the severity of pain

Secondary outcomes

1

Description
Side effects and changes in vital signs
Timepoint
30 and 60 minutes after treatment
Method of measurement
Patient monitoring

Intervention groups

1

Description
intervention group :administration of morphine 0.1 mg /kg and evaluation of pain score and side effects in minutes 0;10;30;60;90;120 of study.
Category

Treatment - Drugs

2

Description
control group :administration of morphine 0.1 mg/kg +12.5 mg of intravenous promethazine and evaluation of pain score and side effects in minutes 0;10;30;60;90;120 of study
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency Department of Hazrate Rasool (S) Educational-Therapeutic Centre
Full name of responsible person
Saieed Abbasi, Medical Doctor
Street address
Emergency department, Hazrate Rasool hospital, Niyayesh street, Sattarkhan
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Shahin Akhondzadeh
Street address
Tehran University of Medical Sciences, Enghelab St.
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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 for research, Tehran 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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Web page address

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