Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of oral oxycodone and intravenous acetaminophen with intravenous morphine sulfate for acute pain management in trauma patients admitted to the emergency department of rasool Hospital, Tehran

Protocol summary

Summary

Pain management in traumatic patients is one of the main debates in the emergency department. Various medications have been prescribed for pain management in these patients. This study has been designed to compare two methods of pain relief in trauma patients with oral oxycodone and intravenous acetaminophen with intravenous morphine sulfate. In this trial, the study population are traumatic patients with pain score of 5 and more, who need pain relief and referred to emergency department of Rasool Akram hospital, Tehran during Jan 2012 and April 2012. Estimated sample size is 150 patients, who will be recruited in the study according to inclusion and exclusion criteria and will randomized in two group: oral oxycodone and intravenous acetaminophen(75 patients) and intravenous morphine sulfate (75 patients). Patients will evaluate by a physician during the study about pain severity and any complication. In this study, pain will be evaluated based on Visual Analog Scale before treatment, 10 minutes later, 30 minutes and 60 minutes after administration of drugs. Besides, the patient's vital signs and possible complications caused by the drugs will be evaluated and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204298104N8**
Registration date: **2012-05-06, 1391/02/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-05-06, 1391/02/17

Registrant information

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Mohammad Amin Zare
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral oxycodone and intravenous acetaminophen with intravenous morphine sulfate for acute pain management in trauma patients admitted to the emergency department of rasool Hospital, Tehran

Public title

Comparison of Oral oxycodone and intravenous

acetaminophen with intravenous morphine sulfate for acute pain in trauma patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: signing informed consent by the participate in the study; age greater than 16 and less than 50 years old; moderate to severe pain caused by trauma (pain score above 5 on the visual Analog scale) and trauma to extremities without head trauma.
Exclusion criteria: history of allergy or intolerance to morphine sulphate or oxycodone; concurrent substance abuse; mild to moderate pain (pain score of less than 5); psychiatric disorders; patients with history of chronic obstructive pulmonary disease, asthma, and ischemic heart disease; reduction in the patient's level of consciousness (GCS score less than 15); patients with low blood pressure (systolic blood pressure less than 90 mmHg); patients with liver dysfunction and pneumothorax.

Age
From **16 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **150**

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
Tehran University of Medical Sciences Ethics Committee

Street address
Sixth floor, Tehran University of Medical Sciences main bulding, Ghods street, Keshavarz Blvd, Tehran, Iran

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Tehran

Postal code
144574311

Approval date
2012-03-04, 1390/12/14

Ethics committee reference number
90/2478/130/د

Health conditions studied

1

Description of health condition studied
trauma

ICD-10 code
XIII

ICD-10 code description
musculoskeletal sysytem and connective tissue diseases

Primary outcomes

1

Description
Pain control

Timepoint
At the begining, 10, 30 and 60 minutes after the administration of the study medications

Method of measurement
Pain score by asking from patient

Secondary outcomes

1

Description
Side effects and changes in vital signs

Timepoint
At the begining, 10, 30 and 60 minutes after the administration of the study medications

Method of measurement
Monitoring the patients

Intervention groups

1

Description
Intervention group :administration of oxicodone 10mg/peroral and acetaminophen 1 gram intravenously and 5 cc streile waterintravenously as placebo and evaluation of pain score and side effects in minutes 0;10;30;60 of study.

Category
Treatment - Drugs

2

Description
Control Group: Administration of 5 mg Morphine sulfate and oral placebo, after 0, 10, 30, 60 minutes pain score and side effects will be evaluated.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Rasool hospital
Full name of responsible person
Mohamad Amin Zare
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Niyayesh street, Sattarkhan, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Shahin Akhondzadeh
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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
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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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