Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of analgesic effect of memantin plus morphin with morphin in patient with lower limb trauma

Protocol summary

Summary

Objectives: Comparing the analgesia effect of morphine and morphine plus memantin in patients with lower limb trauma. Inclusion Criteria: Fracture in lower extremity; GCS=15; VAS≥6 ; ability to talk; stable hemodynamic. Exclusion Criteria: age>65 and age <18; Opium addiction; Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy with analgesic drugs; sensitivity to morphine or memantin; 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 disease. The population of study is included in patients suffering lower extremity fracture, who are admitted suffering severe pain(VAS≥6), requiring analgesia. Sample of Study: According to population of study, 333 patients will be studied in each group. Intervention of Study: Investigation of the analgesic effect of Memantin in patients suffering Limb Trauma. Outcome: The effect on Pain Severity 0, 60, 120, 240, 480 and 720 minutes after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404107751N3**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

Name
Davood Farsi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of analgesic effect of memantin plus morphin with morphin in patient with lower limb trauma

Public title

Pain control in Lower limb traumatic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Fracture in lower extremity; GCS=15; VAS≥6 ; ability to talk; stable hemodynamic. Exclusion Criteria: age>65 and age <18; Opium addiction; Psychological disorder; analgesia administration before admission in Emergency department; chronic therapy

with analgesic drugs; sensitivity to morphine or memantin; 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
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **1000**

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
Iran University of Medical Sciences

Street address
Hemmat highway, next to Milad Hospital

City
Tehran

Postal code

Approval date
2014-04-26, 1393/02/06

Ethics committee reference number
93/105/373/د

Health conditions studied

1

Description of health condition studied
Pain in limb

ICD-10 code
M79.6

ICD-10 code description
Pain in limb

Primary outcomes

1

Description
Pain Severity

Timepoint
0, 60, 120, 240, 480 and 720 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, 60 and 120 minutes after treatment

Method of measurement
Patient monitoring

Intervention groups

1

Description
first group:morphin+memantin 10 mg

Category
Treatment - Drugs

2

Description
second group:morphin+memantin 5 mg

Category
Treatment - Drugs

3

Description
third group:morphin +placebo

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
Esmat Shabani, MD

Street address
Emergency department, Hazrate Rasool hospital, Niyayesh street, Sattarkhan

City
Tehran

2

Recruitment center
Name of recruitment center
Emergency Department of Haftetir Hospital
Full name of responsible person
Esmat Shabani, MD
Street address
Rajaee st.
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Shahre Rey

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyyed Ali Javad Mousavi, MD
Street address
Shahid Hemmat Highway,next to Milad Hospital
City
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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 for research, 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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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