Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous Magnesium Sulfate versus intravenous Sufentanil on the duration of Spinal anesthesia and post-operative pain in patients with leg fracture.

Protocol summary

Summary

Special purpose of the project: Studying the effect of Intravenous magnesium sulfate In comparison with Venous Sufentanil, about the duration block of spinal anesthesia and postoperative pain, in the Patients with shin fracture. This project will be done in double –blind randomized controlled trial method. 70 Patients in the age group of 18 to 58 years, ASA I,II, that refer to the health centers in an elective way, for the leg surgery, are randomly divided into two groups; 1. Recipient of sufentanil intravenous solution. 2. Recipient of intravenous magnesium sulfate solution. exclusion criteria: Spinal absolute and relative contraindications; High ICP; Coagulopathy; Peripheral neuropathy of the lower extremities; Using calcium channel blockers. After embedding peripheral venous cannula 10cc/kg ringer Crystalloid fluid, is infused to the patient. All the patients were going through the spinal anesthesia, With 10mg of the 0.5% Bupivacaine with the needle no.25 and selecting the L4-L5 space and they will undergo a surgery after being sure about the Neuraxial block and lack of understanding the sharpness of the needle in the T10 dermatome. in the group which receives sufentanil, 0.1 kg/h/µ of this Substance should be diluted in 1liter of ringer and after an hour, after ensuring about the completion of Sensory and motor block, Infusion will be done. In the second group, 8 mg/kg/h of the 10% Intravenous magnesium sulfate, should be diluted in one liter of the ringer serum, after an hour, after the ensuring about the completion of Sensory and motor block, Infusion will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022126685N1**

Registration date: **2016-06-04, 1395/03/15**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2016-06-04, 1395/03/15

Registrant information

Name

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Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences.

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Recruitment status

Not enough for processing

Funding source

Ahvaz Jundishapur University Of Medical Sciences,Ahvaz, Iran

Expected recruitment start date

2016-07-28, 1395/05/07

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous Magnesium Sulfate versus

intravenous Sufentanil on the duration of Spinal anesthesia and post-operative pain in patients with leg fracture.

Public title
The effect of intravenous Magnesium Sulfate versus an analgesic on the duration of Spinal anesthesia and post-operative pain in patients with leg fracture.

Purpose
Treatment

Inclusion/Exclusion criteria
Entry requirements; the age group of 18 to 58 years, ASA I,II, BMI: 19-30 Exclusion criteria: Patient refusal; High ICP; Coagulopathy; Skin infection, in the insertion of the needle; Peripheral neuropathy of the lower extremities; Drug and alcohol abuse; Using sedative and antipsychotic drugs and also psychotropic substances; Using calcium channel blockers; Having a history of mental illnesses and also Thyroid Disorders; A history of kidney disorders and cardiac arrhythmias.

Age
From **18 years** old to **58 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Street address
Ahvaz Jondishapoor University of Medical Sciences, Golestan Ave.

City
Ahvaz

Postal code

Approval date
2016-02-13, 1394/11/24

Ethics committee reference number
IR.AJUMS.REC.1394.628

Health conditions studied

1

Description of health condition studied
leg fracture

ICD-10 code
S82.7

ICD-10 code description
Multiple fractures of lower leg

Primary outcomes

1

Description
Sensory and motor block

Timepoint
An hour after the begining the operation

Method of measurement
Modified Bromage Scale

2

Description
pain

Timepoint
After the surgery

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
control group: In the second group, 8mg/kg/h Magnesium sulfate(10% Intravenous), in a quite similar way, should be diluted in 1liter of ringer and after an hour, after ensuring about the completion of anesthesia, Infusion will be done. All the patients were under spinal anesthesia, with 10 mg of Bupivacaine(10%), In a sitting position, with the needle no. 25 and by Selecting the L4-L5 space and Nvragzyal block and failure to understand the sharpness of the needle in T10 dermatom, Patients are undergoing a surgery. After the Spinal anesthesia and During the surgery with five minutes Intervals, Systolic and diastolic blood pressure, The percentage of arterial oxygen and heart rate are monitored and If blood pressure decreases by twenty percent or Systolic blood pressure decreases to less than 100mmHg, they will receive Afrdyn (0.5mg), and If blood pressure decreases to less than 60, they will receive Atropine(0.5mg), The dose will be repeated, If needed. As well, all the patients, during the surgery, will receive Oxygen 4 liters per

minute. In this study, Onset of anesthesia will be evaluated with Pin Prick way and also, Patients interview about heavy and tingling legs. Complete muscular weakness of lower extremity, following the Spinal Anesthesia, Is considered as a starting for point motor block and the duration of the anesthesia, will be evaluated with the Modified bromage scale. In this way, an hour after the start of operation, the sensory and motor block Condition will be evaluated by examining the normal feet and this evaluation will be continued and recorded an interval of every half an hour, by the end of the return of sensory and motor block recovery. Postoperative pain, will be evaluated by Visual Analog Scale(VAS). After the surgery, All the patients are transferred to recovery and until the end of returning from anesthesia, they will be monitored In terms of heart rate, breathing, the amount of oxygen saturation and also blood pressure. Patients' demographic characteristics are collected, such as; weight, age, gender, height and the length of surgery. Considering the end time of anesthesia in recovery, as the origin of Postoperative pain, after 0, 1, 4, 8, 16, 24 hours, compared to the end of anesthesia has been evaluated and registered and in the case of equal VAS (or more than 3), the patients will receive 30 mg/kg Pethidine intravenously. At the end, the first time of requesting analgesic and also, total analgesic consumption, will be recorded.

Category

Treatment - Drugs

2

Description

Intervention group: After embedding Peripheral venous cannula, we infused 10 cc/kg of Ringer crystalloid to the patients. All the patients were under spinal anesthesia, with 10 mg of Bupivacaine(10%), In a sitting position, with the needle no. 25 and by Selecting the L4-L5 space and Nvragzyal block and failure to understand the sharpness of the needle in T10 dermatom, Patients are undergoing a surgery. In the group which receives Sufentanil, in the group which receives sufentanil, 0.1 kg/h/µ of this Substance should be diluted in 1liter of ringer and after an hour, after ensuring about the completion of anesthesia, Infusion will be done. In all participants, Serum levels of creatinine will be measured before the surgery and after the end of surgery, Patients are moved to the recovery room. After the Spinal anesthesia and During the surgery with five minutes Intervals, Systolic and diastolic blood pressure, The percentage of arterial oxygen and heart rate are monitored and If blood pressure decreases by twenty percent or Systolic blood pressure decreases to less than 100mmHg, they will receive Afrdyn (0.5mg), and If blood pressure decreases to less than 60, they will receive Atropine(0.5mg), The dose will be repeated, If needed. As well, all the patients, during the surgery, will receive Oxygen 4 liters per minute. In this study, Onset of anesthesia will be evaluated with Pin Prick way and also, Patients interview about heavy and tingling legs. Complete muscular weakness of lower extremity, following the Spinal Anesthesia, Is considered as a starting for point motor block and the duration of the anesthesia, will be evaluated with the Modified bromage scale. In this way, an hour after the start of operation, the sensory and motor block Condition will be evaluated by examining the normal feet and this evaluation will be continued and recorded an interval of every half an hour, by the end of the return of sensory and motor block recovery. Postoperative pain, will be evaluated by Visual Analog Scale(VAS). After the surgery, All the patients are transferred to recovery and until the end of returning from anesthesia, they will be monitored In terms of heart rate, breathing, the amount of oxygen saturation and also blood pressure. Patients' demographic characteristics are collected, such as; weight, age, gender, height and the length of surgery. Considering the end time of anesthesia in recovery, as the origin of Postoperative pain, after 0, 1, 4, 8, 16, 24 hours, compared to the end of anesthesia has been evaluated and registered and in the case of equal VAS (or more than 3), the patients will receive 30 mg/kg Pethidine intravenously. At the end, the first time of requesting analgesic and also, total analgesic consumption, will be recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Maryam Jafari

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City

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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Maryam Jafari

Street address

Golestan Medical Center, Golestan Ave.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Dr. Nader Saki
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Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave.
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran
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