

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of evaluation of pain control in orthopaedic surgery after adding magnesium sulfate to fentanyl infusion

Protocol summary

Summary

The aim of this study is adding the magnesium sulfate to pain reduction . We assessed the efficacy with VAS. After the approval of ethical committee of University, we obtained a written consent from the patients in a day before surgery. We trained the patients about how to use the visual analogue scale (VAS) . We used the general anesthesia in all patients. We used the same premedication (midazolam 2-3 mg and 1-2 micro/kg Fentanyl) and induction (1/5-2 mg/kg propofol and .5mg/kg atracurium) . After that we use the propofol infusion . After the patient interance to recovery room , The patients were randomly assigned to two groups: case group (magnesium sulfate) and control group . We used the PCIA for all patients . In group 1 (40 patients) we infused 30mg/kg sulfate magnesium in 250 cc sodium chloride (over 10 minute) and then 10 mg/kg for 48 hours. We add the above drugs to fentanyl pump . In control group (40 patients) we infused the 250cc sodium chloride over 10 minutes and then the equal volume of magnesium sulfate were infused. We evaluated the heart rate (HR), mean arterial pressure (MAP) and arterial oxygen saturation during the first 6 hours every 2 hours, then 6, 12 , 18 , 24 and 48 after that . Inclusion criteria : patients with the age group of 20 to 50 years; patients with ASA I, II , orthopedic surgery will be done under the same procedure with General anesthesia and the surgical team are the same . Exclusion criteria : Patients who have major disease of liver; kidney; cardiovascular; asthma and COPD ; patients were treated with calcium channel blocker. In patient with VAS > 4 and continuous and persistent pain, additional 50 micro fentanyl are to be considered. VAS and drug prescribed will be recorded at this time. The patient's pain have been assessed with visual analogue scale (VAS) and will be recorded at 1 , 6 , 12 , 18 , 24 and 48 hours. The patient,s sedation have been assessed with ramsay sedation score in 1 , 6 , 12 , 18 , 24 and 48 hours. We will have evaluated the magnesium serum level at 12 and 24 hours.

Anesthesiologist who is not aware of the patient group is responsible for the assessment of the amount of sedation, pain , fentanyl consumption and hemodynamic variables. Side effects such as hypotension (SBP < 100 mmhg) , heart rate <60 b/min, nausea and vomiting have been recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411017984N21**

Registration date: **2015-01-04, 1393/10/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-04, 1393/10/14

Registrant information

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Farnad Imani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

V ice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

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

Clinical trial of evaluation of pain control in orthopaedic surgery after adding magnesium sulfate to fentanyl infusion

Public title

Clinical trial of evaluation of pain control in orthopaedic surgery after adding magnesium sulfate to fentanyl infusion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients with the age group of 20 to 50 years; patients with ASA I, II , orthopedic surgery will be done under the same procedure with General anesthesia and the surgical team are the same . Exclusion criteria : Patients who have major disease of liver; kidney; cardiovascular; asthma and COPD ; patients were treated with calcium channel blocker.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences.

Street address

Hemat "Exp". Way, Vice chancellor for research, Iran University of Medical Sciences, beside Milad Tower, Tehran

City

Tehran

Postal code

1443763187

Approval date

2014-10-19, 1393/07/27

Ethics committee reference number

105412-20410-30-01-92

Health conditions studied**1****Description of health condition studied**

Clinical trial of evaluation of pain control in orthopaedic surgery after adding magnesium sulfate to fentanyl infusion

ICD-10 code

XIII

ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

Primary outcomes**1****Description**

Pain

Timepoint

1 , 6 , 12 , 18 , 24 , 48

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes**1****Description**

Sedation

Timepoint

First and 1,6,12,18,24,48 hours later

Method of measurement

Ramsay score

Intervention groups**1****Description**

Group 1 (magnesium sulfate) 40 patients, we infused fentanyl plus magnesium sulfate in ordered below: 30mg/kg sulfate magnesium in 250 cc sodium chloride (over 10 minute) and then 10 mg/kg for 48 hours.

Category

Treatment - Drugs

2

Description

In control group (40 patients) we infused the 250cc sodium chloride over 10 minutes and then the equal volume of magnesium sulfate were infused.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Karim Hematy

Street address

Niayesh "St", Sattarkahn "St, 4th Floor, Department of pain, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Iran University of Medical Sciences

Full name of responsible person

Ali Javad Mousavi

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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Karim Hemati

Position

Second administrator- Associate professor of anesthesia , pain fellow ship

Other areas of specialty/work

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Full name of responsible person

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Position

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty