

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A Comparison between the quality of controlled hypotension induced by Magnesium sulfate & Remifentanil in Lumbar PSF surgery

Protocol summary

Summary

The main objective of this project is the study of magnesium sulfate capability for inducing controlled hypotension for reducing blood loss during posterior fusion of spine and comparing that with the effects of remifentanil. The study designed as a prospective randomized double blind clinical trial in two groups (magnesium & remifentanil). The inclusion criteria includes: patients with 20- 60 years old, and ASA I & II physical status in candidates for posterior fusion of lumbar spine. Patients with the history of systemic cardiovascular, hepatic and renal diseases as well as those with allergic reaction to magnesium and remifentanil were excluded. Then 40 patients were allocated randomly into two equal groups. After induction of anesthesia and placing the patients in prone position and making sure that they are hemodynamically stable, in group I, a loading dose of magnesium (50 mg/kg) was administered in 10 min and then a 15mg/kg were infused continually during operation. And in the second group, infusion of remifentanil 0.1- 0.2µg/kg/min instead of magnesium sulfate was used. The remaining anesthetic drugs and techniques are the same for both groups. The aim of this intervention is the reduction of mean arterial pressure to 60-75 mmHg. If the success could not be achieved in 10 min, infusion of TNG will be started and documented for comparison between groups. In addition, amount of blood loss, total fluid therapy, and need for transfusion, urine output, satisfaction of surgeons from the surgical field, and hemodynamic variables will be recorded. Complications such as arrhythmias, bradycardia, hypotension and therapeutic intervention for them also shall be recorded and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111138091N1**

Registration date: **2012-02-06, 1390/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-06, 1390/11/17

Registrant information

Name

Kourosh Farazmehr

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice chancellor of TUMS

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison between the quality of controlled hypotension induced by Magnesium sulfate & Remifentanil in Lumbar PSF surgery

Public title

Controlled hypotension due to magnesium sulfate and remifentanyl

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: Individuals between 20-60 years old, candidate for PSF surgery, ASA I & II physical status, signing informed consent of study
Exclusion Criteria includes: Allergic reaction to drugs, Liver, renal, cardiovascular failure, Ventricular and atrial arrhythmia and conduction heart disorders, Opioid consumption and drug abuse, Chronic therapy with opioids, NSAIDs and calcium channel blockers

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Faculty of Medicine, Tehran
University of Medical Sciences

Street address

Keshavarz Blvd, Poursina St.

City

Tehran

Postal code

14736

Approval date

2010-03-02, 1388/12/11

Ethics committee reference number

42114

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

Instability of Lumbar Spine

ICD-10 code

S33.3

ICD-10 code description

Dislocation of other & unspecified parts of lumbar spine & pelvis

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

Mean arterial pressure

Timepoint

Continuous monitoring

Method of measurement

Invasive blood pressure monitoring with transducer and monitoring device

2**Description**

Blood loss

Timepoint

During operation

Method of measurement

Calculating the amount of blood in the suction, surgical field and towels in cc

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

Prevalence of transfusion in two groups

Timepoint

End of surgery

Method of measurement

Recording patients who need for transfusion and number of blood packs

2**Description**

Arrhythmia

Timepoint

During operation

Method of measurement

Continuous ECG monitoring

3**Description**

Bradycardia

Timepoint

During operation

Method of measurement

Continuous ECG monitoring

4

Description

Hypotension

Timepoint

During operation

Method of measurement

Continuous IBP monitoring

5

Description

Prevalence of need for TNG administration

Timepoint

Throughout the operation

Method of measurement

Recording patients who need TNG for controlling blood pressure

Intervention groups

1

Description

In group 1, Magnesium sulfate was administered with loading dose of 50mg/kg IV in 100cc Normal saline over 10 min, then with infusion pump the maintenance dose of magnesium sulfate (15mg/kg/h) was administered until 30 min before the end of operation.

Category

Treatment - Drugs

2

Description

In the second group remifentanyl was administered until the end of operation with maintenance dose of 0.1- 0.2 microgram/kg /min IV with infusion pump.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Orthopedic & neurosurgical clinic in Hazrate Rasoul Hospital

Full name of responsible person

Kourosh Farazmehr

Street address

Rasoul-e-Akram hospital, Niayesh St, Satar Khan Av.

City

Tehran

2

Recruitment center**Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Mohammad Reza Ghodrati

Street address

Behafarin St, Karim Khan Av.

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Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research vice-chancellor of Medicine faculty, Tehran university of medical sciences

Full name of responsible person

Dr. Sahin Akhondzade Basti

Street address

Medical school, Porsina St, Keshavarz Blvd.

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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

Research vice-chancellor of Medicine faculty, 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

Contact**Name of organization / entity**

Tehran university of medical sciences

Full name of responsible person

Kourosh Farazmehr

Position

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Person responsible for scientific inquiries

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Person responsible for updating data

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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