

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison the effects of intravenous remifentanil and dexmedtomidine in post spinal fusion surgery

Protocol summary

Summary

Considering the importance of an appropriate hemodynamic control in patients undergoing spinal fusion surgeries especially heart rate and blood pressure for improvement in surgical field , the necessity of findings drugs with the ability to control the above mentioned parameters has increased. Remifentanil is a short acting and potent opioid which has used in different surgeries for blood pressure and heart rate control. Dexmedtomidine as an alfa-2 agonist has been chosen in this study with this hypothesis that could have a reliable control in blood pressure and heart rate. The study has designed to perform in 50 patients candidated for spinal fusion surgery with ASA class I&II and age between 15-65 years who have signed the informed consent, who had not any heart, lung, kidney and coagulopathy diseases. After block randomization and with randomized number table usage they were grouped to receive either remifentanil infusion as 0.2 micro/Kg/Min or Dexmedtomidine infusion as 1 micro/Kg/hr. Hear rate, blood pressure, oxygen saturation will be measured before and after anesthesia induction, in 1,2 and 3 hours later, after extubation and up to 1 hour in recovery room. Blood loss, surgeon satisfaction from surgical field, anesthesia emergence and extubation time, sedation and pain score in recovery, discharge time and first analgesic requirement time up to 6 hours will also be measured in recovery. The results will be recorded in prepared questionnaire and will be evaluated later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012081410336N3**

Registration date: **2012-12-28, 1391/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-28, 1391/10/08

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences, vice chancellor for research

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of intravenous remifentanil and dexmedtomidine in post spinal fusion surgery

Public title

Comparison remifentanil and dexmedtomidine effects in post spinal fusion surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1-Patients between 15-65 years 2-With American Society of anesthesiologist grade I& II 3-Candidated for posterior spinal fusion surgery maximally at 3 levels 4-sign informed consent Exclusion criteria: Having heart, lung, renal and hepatic diseases, coagulopathy No sign the informed consent

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Tehran university of medical sciences

Street address

Keshavarz bld-Ghods building

City

Tehran

Postal code

Approval date

2012-04-20, 1391/02/01

Ethics committee reference number

9890

Health conditions studied

1

Description of health condition studied

spinal fusion surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

blood pressure

Timepoint

each hour

Method of measurement

mmHg-automatic device

Secondary outcomes

1

Description

heart rate

Timepoint

each hour

Method of measurement

beat/min-automatic device

Intervention groups

1

Description

Prescribe two different drugs and monitor their hemodynamic effects 1- first group will receive remifentanil infusion as an anesthesia maintenance with 0.2micro/Kg/min dosage and monitor for hemodynamic changes

Category

Treatment - Drugs

2

Description

Second group will receive dexmedtomidine infusion during surgery as anesthesia maintenance regimen with 1 micro/Kg/hr dosage and will be monitored.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasul Medical Complex

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Chancellor of research/Dr Akbar Fotuhi

Street address

Enghelab St, Poorsina Ave

City

Tehran

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****Contact****Name of organization / entity**

Tehran university of medical sciences

Full name of responsible person

poupak Rahimzadeh

Position

Assistant professor

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Web page address**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*