Comparative study of the effect of two different doses of remifentanil on bleeding control in lumbar fusion surgery under general anesthesia

Protocol summary

Study aim
Comparative study of the effect of two different doses of remifentanil on bleeding control in lumbar fusion surgery under general anesthesia

Design
Clinical trial without control group with parallel, randomized, phase 3 groups on 110 patients A random number table was used for randomization.

Settings and conduct
This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. The first group will be treated with a dose of 0.1 remifentanil and the second group will be treated with a dose of 0.3 remifentanil. Patients' blood pressure and bleeding were measured and compared in two groups.

Participants/inclusion and exclusion criteria
Inclusion criteria: The patient agrees to participate in the study, the patient is a candidate for posterior spinal fusion surgery at levels 1 and 2, does not take antihypertensive drugs
Exclusion criteria: change in surgery technique and anesthesia for various reasons, occurrence of unwanted hemodynamic complications due to surgery technique, severe cardiovascular disease

Intervention groups
Intervention group 1: Patients in this group undergo vertebral fusion surgery under general anesthesia and receive remifentanil at a dose of 0.1 μg / kg. Patients' blood pressure and bleeding during surgery and recovery will be measured every 30 minutes. Intervention group 2: Patients in this group undergo vertebral fusion surgery under general anesthesia and receive remifentanil at a dose of 0.3 μg / kg. Patients' blood pressure and bleeding during surgery and recovery will be measured every 30 minutes.

Main outcome variables
Blood pressure and bleeding

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20200217046523N12
Registration date: 2021-03-09, 1399/12/19
Registration timing: prospective

Last update: 2021-03-09, 1399/12/19
Update count: 0

Registration date
2021-03-09, 1399/12/19

Registrant information
Name
Aryan Rafiee Zadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 83 3837 1582
Email address
rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-20, 1400/01/31

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of two different doses of remifentanil on bleeding control in lumbar fusion surgery under general anesthesia

Public title
Remifentanil and control bleeding during lumbar fusion surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- Patient consent to participate in the study
- Patient candidate for posterior spinal fusion surgery at levels 1 and 2
- Not taking antihypertensive drugs

Exclusion criteria:
- Changing the technique of operation and anesthesia for various reasons
- Unwanted hemodynamic complications due to surgical technique
- Severe cardiovascular disease

Age
- From 18 years old to 70 years old

Gender
- Both

Phase
- 2-3

Groups that have been masked
- No information

Sample size
- Target sample size: 110

Randomization (investigator's opinion)
- Randomized

Randomization description
- Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group. The researcher begins to read the numbers in a predetermined manner and the patients are divided.

Blinding (investigator's opinion)
- Not 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 Isfahan University of Medical Sciences

Street address
- Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City
- Isfahan

Province
- Isfehan

Postal code
- 8174673461

Approval date
- 2021-02-06, 1399/11/18

Health conditions studied

1

Description of health condition studied
- Spinal fusion surgery

ICD-10 code
- H53.32

ICD-10 code description
- Fusion with defective stereopsis

Primary outcomes

1

Description
- Blood pressure

Timepoint
- Every 30 minutes during surgery and recovery

Method of measurement
- Measured by the device

2

Description
- Bleeding

Timepoint
- Every 30 minutes during surgery and recovery

Method of measurement
- Count the number of gases

Secondary outcomes
- empty

Intervention groups

1

Description
- Intervention group 1: Patients in this group undergo vertebral fusion surgery under general anesthesia and receive remifentanil at a dose of 0.1 μg / kg. Patients' blood pressure and bleeding during surgery and recovery will be measured every 30 minutes.

Category
- Treatment - Drugs

2

Description
- Intervention group 2: Patients in this group undergo
vertebral fusion surgery under general anesthesia and receive remifentanil at a dose of 0.3 μg / kg. Patients’ blood pressure and bleeding during surgery and recovery will be measured every 30 minutes.

**Category**
Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Mehrdad Masoudifar
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
masoudifar@med.mui.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0042
Email
haghjoo.sh@med.mui.ac.ir

**Grant name**

**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?
Yes

**Title of funding source**
Esfahan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
empty

**Country of origin**

**Type of organization providing the funding**
Academic

**Person responsible for general inquiries**

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehrdad Masoudifar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3337 7986
Email
masoudifar@med.mui.ac.ir

**Person responsible for scientific inquiries**

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehrdad Masoudifar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3337 7986
Email
masoudifar@med.mui.ac.ir
Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehrdad Masoudifar
Position
Associate professor
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City
Isfahan
Province
Isfahan
Postal code
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+98 31 3337 7986
Email
masoudifar@med.mui.ac.ir

Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after people have requested.

When the data will become available and for how long
Six months after publishing the results.

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments