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
rafiiezadeh.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

Ethics committee reference number
IR.MUI.MED.REC.1399.1025

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
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8174673461
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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 Haghioo
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
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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
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
empty
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
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Position
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Latest degree
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Other areas of specialty/work
Anesthesiology
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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
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
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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