

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

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

Isfahan

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 remifentanyl 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

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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**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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity

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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