Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of dexmedetomidine and propofol versus remifentanil and propofol on rate of discharge from recovery in patients candidate for posterior lumbar spine fusion surgery

Protocol summary

Summary

Objectives: Recovery units in the operating rooms perform a part of the work done in the post anesthesia care unit since the patients transfer to the relative ward after stabilization of cardiovascular and respiratory state, maintaining full consciousness, and ability to move limbs. Discharge rate of these patients and the sustainability of organs can vary depending on the type of anesthesia and used drugs and affects discharge of patients from recovery. To improve hemodynamic parameters and consciousness of patients undergoing posterior lumbar spine fusion surgery, we compare two combinations include dexmedetomidine and propofol versus remifentanil and propofol. Design: Block randomization, double blind, without placebo, single center, trial phase 2, including 20 patients who undergo posterior lumbar spine fusion surgery. Setting and conduct: Fentanyl, 2 µg/kg, intravenous, to induce anesthesia. Atracurium, 0.2 mg/kg, intravenous, to induce anesthesia. Participants including major eligibility criteria: All women who are supposed to undergo posterior lumbar spine fusion surgery. Intervention: Dexmedetomidine, 0.1 µg/kg, intravenous. Remifentanil, 1 µg/kg, intravenous. Propofol, 2 mg/kg, intravenous, to induce anesthesia. Main outcome measures: Activity level, Respiration, Consciousness, Blood pressure, O2 saturation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102819715N1**
Registration date: **2014-12-24, 1393/10/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-24, 1393/10/03

Registrant information

Name

Arash Pourbakhshandeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2326

Email address

alimyan.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of dexmedetomidine and propofol versus remifentanil and propofol on rate of discharge from recovery in patients candidate for posterior lumbar spine fusion surgery

Public title

Comparison of dexmedetomidine versus remifentanil on

rate of discharge from recovery in patients candidate for posterior lumbar spine fusion surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction; Age between 18-65 years old; Patients candidate for posterior lumbar spine fusion surgery; Elective surgery; No history of spinal surgery. Exclusion criteria: Addiction to drugs or alcohol; Sensitivity to drugs use in this study; Long-term and chronic use of painkillers; Respiratory and cardiovascular diseases; Unpredictable events such as severe bleeding.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

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 Iran University of Medical Sciences

Street address

Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-10-29, 1392/08/07

Ethics committee reference number

92/130/1640

Health conditions studied

1

Description of health condition studied

Fusion of spine

ICD-10 code

M43.8

ICD-10 code description

Other specified deforming dorsopathies

Primary outcomes

1

Description

Activity level

Timepoint

Every ten minutes after extubation

Method of measurement

Aldrete score

2

Description

Respiration

Timepoint

Every ten minutes after extubation

Method of measurement

Aldrete score

3

Description

Consciousness

Timepoint

Every ten minutes after extubation

Method of measurement

Aldrete score

Secondary outcomes

1

Description

Blood pressure

Timepoint

Every ten minutes after extubation

Method of measurement

Sphygmometer

2

Description

O2 saturation

Timepoint

Every ten minutes after extubation

Method of measurement

Pulse oximeter

Intervention groups

1

Description
Intervention 1. Dexmedetomidine, 0.1 µg/kg, intravenous.
Category
Treatment - Drugs

2

Description
Intervention 2. Remifentanil, 1 µg/kg, intravenous.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool-e Akram hospital
Full name of responsible person
Arash Pourbakhshandeh
Street address
Rasool-e Akram hospital, Niyayesh street, Satarkhan street, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Arash Pourbakhshandeh
Position
Anesthesiology assistant
Other areas of specialty/work
Street address
Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
Dr.pourbakhshandeh@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Arash Pourbakhshandeh
Position
Anesthesiology assistant
Other areas of specialty/work
Street address
Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 6435 2326
Fax
Email
Dr.pourbakhshandeh@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Arash Pourbakhshandeh
Position
Anesthesiology assistant
Other areas of specialty/work
Street address

Headquarters building, 5th floor, intersection of Sheikh Fazl-Allah Noori and Shahid Chamran, Western Hemmat highway, Tehran, Iran
City
Tehran
Postal code
Phone
00
Fax
Email
Dr.pourbakhshandeh@gmail.com
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