

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the Effect of Ketamine Infusion with Dexmedetomidine Infusion during Postoperative Fusion of Lumbar Vertigo in Acute Post-Operative Pain.

Protocol summary

Study aim

Comparison of the Effect of Ketamine Infusion with Dexmedetomidine Infusion during Postoperative Fusion of Lumbar Vertigo in Acute Post-Operative Pain.

Design

Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct

The study population consisted of patients who underwent PSF surgery in Rasoul Hospital in year 97. This study was a double-blind randomized clinical trial on 87 patients undergoing PSF surgery At Hazrat-e-Rasool Hospital, Tehran, have been admitted. The placement of the three groups at the start of the study will be randomized; the selected patients will be divided into three groups: ketamine, dexmedmotidine and control group.

Participants/Inclusion and exclusion criteria

Entry criteria includes candidates for performing PSF surgery with ASA1 or ASA2, and exclusion criteria including a history of psychiatric illness, systemic diseases such as heart failure, liver, kidney, lung, infectious disorder, abnormalities and addicted patients.

Intervention groups

Bradycardia is considered to be a moderate arterial pressure of more than 20% by a decrease of more than 20% of the heart rate per minute (relative to the heart rate constant) and hypotension. If bradycardia is present, atropine will be administered at a dose of 0.01 mg / kg and, Infused ephedrine 0.1mg / kg is used intravenously.

Main outcome variables

Satisfaction rate of analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180723040570N2**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Nasim Nikoubakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 9854

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-05, 1398/05/14

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Ketamine Infusion with Dexmedetomidine Infusion during Postoperative Fusion

of Lumbar Vertigo in Acute Post-Operative Pain.

Public title

Comparison of the Effect of Ketamine Infusion with Dexmedetomidine Infusion during Postoperative Fusion of Lumbar Vertigo in Acute Post-Operative Pain.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Entry criteria included candidates for PSF surgery and ASA1 or ASA2

Exclusion criteria:

history of the disease Psychiatry systemic diseases such as heart failure, liver, kidney, lung infectious disorder consciousness abnormalities addicted patients

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 87

Randomization (investigator's opinion)

Randomized

Randomization description

At first, an anesthetist examines patients and then evaluates patients on entry and exit criteria and, if they are satisfied, enter the study. Patients were randomly divided into 3 groups: ketamine (29 patients), doxedmodytidine (29), and control group (29).

Blinding (investigator's opinion)

Double blinded

Blinding description

The placement of the three groups at the start of the study will be randomized; the selected patients will be divided into three groups: ketamine, dexmedmotidine and control group. The blind is such that the only researcher knows the division of the three groups, and the participant is careful of the analyst assessor and the safety and monitoring committee is completely unaware.

Placebo

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

Amirabad

City

Tehran

Province

Tehran

Postal code

1438816391

Approval date

2018-10-26, 1397/08/04

Ethics committee reference number

IR.IUMS.FMD.REC.1397.213

Health conditions studied

1

Description of health condition studied

Posterior fusion surgery of the lumbar spine

ICD-10 code

G54

ICD-10 code description

Nerve root and plexus disorders

Primary outcomes

1

Description

Acute pain after surgery

Timepoint

Enter your recovery & 2&4&6&12 after surjury

Method of measurement

pain ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: ketamin Infusion is administered as an infusion at a dose of 0.1 mg / kg per hour.The consumable ketamines are all manufactured by Rotex Germany.As mentioned, the method of administration of the drug is infusion and the duration of administration from the beginning to the end of surgery.

Category

Treatment - Drugs

2

Description

Intervention group2: dexmedetomidine Infusion is administered as an infusion at a dose of 0.2 mg / kg per hour.Consumer dexmedetomidines are all manufactured by Exir Iran and manufactured in Boroujerd factory.As mentioned, the method of administration of the drug is infusion and the duration of administration from the beginning to the end of surgery.

Category

Treatment - Drugs

3**Description**

Control group:This group of patients does not receive any analgesic during surgery.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasool-Akram Hospital

Full name of responsible person

Mohamad Saleh Sadri

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Painresearch.center@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malakouti

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Nasim Nikoubakht

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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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available