# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**
nikoobakht.n@iums.ac.ir

**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 conciousness 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), doxedmodyntidine (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 surjery
**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

**Street address**

Satarkhan

**City**

Tehran

**Province**

Tehran

**Postal code**

1438814648

**Phone**

+98 21 6435 2325

**Email**

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

**Street address**

Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86709

**Email**

malakouti.k@iums.ac.ir

**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

**Street address**

No.24,kashfian ave.,sheykhbahayy ave.,molasadra ave.,tehran town

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 8862 9854

**Fax**

**Email**

nikoobakht.n@iums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nasim Nikoubakht

**Position**

Associate professor

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Specialist

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nasim Nikoubakht

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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nikoobakht.n@iums.ac.ir

## 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