

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of adding Dexmedetomidine to fentanyl for pain management after spinal fusion surgery using intravenous patient controlled analgesia pumps

Protocol summary

Study aim

The effect of adding Dexmedetomidine to fentanyl for pain management after spinal fusion surgery using intravenous patient controlled analgesia pumps

Design

double blind clinical trial in Ayatollah Kashani Hospital in Isfahan. Patients undergoing spinal fusion surgery who are eligible for inclusion in the study are randomly divided into two groups: case (dexmedetomidine - fentanyl) and control group (fentanyl - placebo). The sample size In total, 66 people in this study will be studied in two groups of 33.

Settings and conduct

At the end of surgery, for both groups, an intravenous analgesic pump is inserted. Then, dexmedetomidine is 0.5 mcg / kg and its equivalent is 0.9% normal saline in both groups. Fentanyl with a base dose of 0/5 mcg/kg and then infusion with an intravenous analgesic pump for the first 24 hours after surgery with the desired setting will be used. Immediately after the patient's position is converted, a dose of bolus is injected into the patient and the infusion of the drug begins at recovery. The measured parameters are examined and the recorded results are analyzed using appropriate statistical tests and SPSS 21.

Participants/Inclusion and exclusion criteria

Entry criteria include: 1- Candidate for posterior fusion surgery of the lumbar spine and thoracic spine 2- Age between 20 and 70 years 3-patients with ASA 1 or 2 4. Satisfaction to participate in the study 5- Educable and have the ability to cooperate. Non-inclusion criteria include opioid susceptibility and known sensitivity to dexmedetomidine.

Intervention groups

dexmedetomidine is 0.5 mcg / kg and its equivalent is 0.9% normal saline in both groups. Fentanyl with a base dose of 0.5 mcg /kg.

Main outcome variables

Age, Sex, Intensity of pain nausea,Vomit Taking ondansetron level of consciousness RR,HR, SPO2 SBP,DBP,MBP Patient Satisfaction

General information

Reason for update

Acronym

Dexmedetomidine- Fentanyl on postoperative pain management

IRCT registration information

IRCT registration number: **IRCT20110402006115N4**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **retrospective**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Mojtaba Rahimi Varposhti

Name of organization / entity

Esfahan medical university

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 1532

Email address

rahimi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

The effect of adding Dexmedetomidine to fentanyl for pain management after spinal fusion surgery using intravenous patient controlled analgesia pumps

Public title

Effect of Dexmedetomidine- Fentanil on postoperative pain of spine surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The candidate for the posterior fusion of the lower back and the thoracic spine Age range 20 to 70 years Patients ASA 1 or 2 Satisfaction to participate in the study Educable and have the ability to cooperate

Exclusion criteria:

History of acute allergic reaction to Dexmedetomidine or Fentanil Patients with mental and physical disabilities in the application of pain pumps The presence of any moderate to severe CVD and respiratory instability

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the individuals referred for spinal surgery who have criteria for entering the study were identified and placed randomly into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The pumps are provided by an anesthetist technician according to the patient's specifications and are available to the researcher. The investigator is unaware of the content inside the pump

Placebo

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

hezar jerib ave. Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

IR.MUI.REC.1396.3.719

Health conditions studied**1****Description of health condition studied**

spinal surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain score base on VAS criteria

Timepoint

Start logging in to recovery, every hour to 24 hours

Method of measurement

VAS CRITERIA SCORE

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: dexmedetomidine 0.5 mcg/kg + fentanyl 0.5 mcg/kg in PCA infusion pump for 24 hours after surgery. The required amount is calculated separately for each patient.

Category

Treatment - Drugs

2

Description

Control group: saline normal 0.9 % + fentanyl 0.5 mcg/kg in PCA infusion pump for 24 hours after surgery. The required amount is calculated separately for each patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital of Isfahan

Full name of responsible person

Mehdi Izadi

Street address

Kashani st.

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8143764471

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mimi_izadi2@yahoo.com

2

Recruitment center

Name of recruitment center

Alzahra hospital of Isfahan

Full name of responsible person

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Phone

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Email

mimi_izadi2@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mojtaba Rahimi

Street address

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City

Isfahan

Province

Isfahan

Postal code

8143764471

Phone

+98 31 3620 1293

Email

rahimi@med.mui.ac.ir

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

50

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

Dr Mojtaba Rahimi

Position

Faculty of Isfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Dissatisfaction with the participants in the study

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data will be available after the end of the study

When the data will become available and for how long

year 2019

To whom data/document is available

Doctors and especially anesthesiologists

Under which criteria data/document could be used

For use in future studies

From where data/document is obtainable

Library of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Fill in the application form to access the study

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mojtaba Rahimi

Position

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Latest degree

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