Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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 (dexmedmotidine - 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, dexmedmotinidine 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

dexmedmotinidine 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- Fentanil 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)

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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
Isfehan
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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2

Recruitment center
Name of recruitment center
Alzahra hospital of Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Anesthesiology
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Person responsible for updating data

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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 anesthetists
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