Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the analgesic effect of intrathecal dexmedetomidine versus fentanyl in opioid dependence undergoing lower limb orthopedic surgery

Protocol summary

Study aim

Comparison of the effect of intrathecal dexmedetomidine and fentanyl on postoperative analgesia in opioid patients during orthopedic lower limb surgery on postoperative pain

Design

A Clinical trial of 25 patients with three treatment paralll groups (receiving fentanyl and dexmedetomidine and normal saline added to spinal bupivacaine), double-blind, randomized using Random allocation software

Settings and conduct

The spinal anaesthesia will be performed in a sitting position by an anesthesiologist . Patients will be randomly divided into 3 groups (25 people). Then, hemodynamic parameters of patients in addition to baseline values at times 2,5,14,15,24 minutes and then measured every 14 minutes to an hour as well as 2 times in recovery and will be recorded.

Participants/Inclusion and exclusion criteria

Drug-dependent patients 18-65 years with ASA II, I Candidate for lower limb orthopedic surgery under spinal anesthesia Exclusion criteria:Emergency surgery, patients with severe valvular heart disease Patients with psychological disorders,Patients with a history of seizures,Patients with ASA greater than II,Patients with allergies to prescription drugs,Patients with a ban on spinal anesthesia (coagulation problems, high ICP, sepsis, infection at the injection site),Patients with neurological defects, Patients who fail the block and need to induce general anesthesia.

Intervention groups

The first group will receive 12.5 mg bupivacaine 0.5% hyperbaric with 5 micrograms Dexmedetomidine The second group will receive 12.5 mg bupivacaine with 25 micrograms fentanyl The third group will receive 12.5 mg bupivacaine and 0.5 cc normal saline

Main outcome variables

The severity of postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110313006044N4**
Registration date: **2020-09-24, 1399/07/03**
Registration timing: **prospective**

Last update: **2020-09-24, 1399/07/03**
Update count: **0**

Registration date

2020-09-24, 1399/07/03

Registrant information

Name

Hashem Jarineshin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

hjarineshin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-30, 1399/07/09

Expected recruitment end date

2020-10-30, 1399/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the analgesic effect of intrathecal dexmedetomidine versus fentanyl in opioid dependence undergoing lower limb orthopedic surgery

Public title
Evaluation of adding intrathecal fentanyl and dexmedetomidine on postoperative analgesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Addict patients with aged 18-65 years andASA II, I Candidate for lower limb orthopedic surgery under spinal anesthesia

Exclusion criteria:
Emergency surgeries Patients with severe valvular heart disease Patients with psychological disorders Patients with a history of seizures Patients with ASA > II Patients with a history of allergy tothe drugs used Patients with a ban on spinal anesthesia (coagulation problems, high ICP, sepsis, infection at the injection site) Patients with neurological defects Patients who fail the block and need to induce general anesthesia

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation was performed based on Random allocation software and based on that even numbers were considered for dexmedetomidine and odd numbers were considered for fentanyl accordingly. The numbers were placed in sealed envelopes and returned by someone other than the procedure performer. Anesthesia was performed by an anesthesiologist and anesthesia resident in charge of data collection and the patients both did not know about the injectable drug and how it was randomized.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to eliminate bias from patient's awareness or anesthesia assistant and person who evaluate the results and its possible impact on the outcome of the study, the study will be conducted in a double-blind condition. After receiving written informed consent from patients, spinal anesthesia was done by anesthesiologist, then relevant information was recorded in the questionnaire by the anesthesiologist who was not aware of the injection of the drugs. It is obvious that the patient and the anesthesiologist were not aware of the type of drug being administered.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee Of Hormozgan University Of Medical Sciences

Street address
Jomhuri Blvd, Shahid Mohammadi Hospital

City
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

Approval date
2019-10-13, 1398/07/21

Ethics committee reference number
IR.HUMS.REC.1398.240

Health conditions studied

1

Description of health condition studied
Lower limb sugary

ICD-10 code
S82.9

ICD-10 code description
Unspecified fracture of lower leg

Primary outcomes

1

Description
Postoperative analgesia

Timepoint
Patients' pain intensity is measured and recorded based on visual analog scale (VAS) in recovery during 2,4,6,12 hours after surgery.

Method of measurement
Patients' severity of pain is based on the Visual Analogues Scale, with the left side indicating no pain and the right side showing the number "10" indicating the most severe pain. Score style 1-3 indicates mild pain, 4-7 moderate pain, severe pain 8-10), duration of analgesia

from time to block until patient requests for analgesics

Secondary outcomes

1

Description
Side effects after surgery including nausea and vomiting and...
Timepoint
During surgery and in recovery between 2,4,6,12 hours after surgery is measured and recorded
Method of measurement
Patient dissatisfaction

Intervention groups

1

Description
First Intervention group: 12.5 mg bupivacaine 0.5% hyperbaric with 5 micrograms dexmedetomidine via intrathecal injection
Category
Treatment - Drugs

2

Description
Second Intervention group: 12.5 mg bupivacaine 0.5% hyperbaric with 25 micrograms fentanyl(ROTEXMEDICA 0.5 mg/10ml 22946TRITTAU. Germany) via intrathecal injection
Category
Treatment - Drugs

3

Description
Control group: 12.5 mg bupivacaine and 0.5 cc Normal saline via intrathecal injection
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital Of Hormozgan University of Medical Sciences
Full name of responsible person
Hashem Jarineshin
Street address
Jomhuri Blvd, Shahid Mohammadi Hospital
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Timur Aghamolaei
Street address
Deputy of research and technology, East Side, Bandar Abbas Hospital, Bandar Abbas
City
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Hashem Jarineshin
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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
All data can be shared

When the data will become available and for how long
Starting the post-access period of the paper was accepted

To whom data/document is available
All researchers

Under which criteria data/document could be used
All researchers

From where data/document is obtainable
Correspondence Dr Hashim Jarineshin contact by email hjarineshin@yahoo.com

What processes are involved for a request to access data/document
Details are available within a week at most

Comments