

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 parallel 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 and ASA 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 to the 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 Committee 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

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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

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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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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