Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparsion of the effect of dexmedetomidine and bupivacaine with morphine and bupivacaine on block quality in leg fracture surgeries under epidural anesthesia

Protocol summary

Study aim
Comparsion of the Effect of Dexmedetomidine and Bupivacaine with Morphine and Bupivacaine on Block Quality in Leg fracture surgeries under Epidural Anesthesia

Design
Clinical trial with control group, parallel group, double-blind, randomization using a random number table

Settings and conduct
The present study was carried out in the Imam Khomeini hospital, Ahwaz and included 80 patients in the age group of 18 to 60 years. Patients were assigned to receive a lumbar epidural containing bupivacaine0.5%, 12ml+ morphine 2mg/kg, or bupivacaine 0.5% 12ml+dexmedetomidine 1µg/kg.

Participants/Inclusion and exclusion criteria
Entry criteria included: Patients aged 18-60 years old with anesthesia risk ASA I, II Exclusion criteria included: 1-Dissatisfaction with the epidural block 2. Patients dependent on each psychiatric drug 3 patients had allergies to the study drugs. 4. Patients with neurological and neuromascular diseases and coagulation disorders. 5. Patients who needed an analgesic drug during surgery. 6. Patients whose epidural blocks failed and under general anesthesia 7-Pregnant women

Intervention groups
Group I consisted of patients who received 12 ml of 0.5% bupivacaine hydrochloride plus dexmedetomidine (B+D) 1µg/kg while Group II patients received 12 ml of 0.5% bupivacaine hydrochloride plus morphine 2mg/kg (B+M)

Main outcome variables
The time to reach of the sensory block is also recorded until the sensory level reaches T12, the duration of the sensory block is recorded as long as the sensory level returns to L5, Also, to evaluate postoperative pain and the time of the first request for analgesia, Visual Analogue Scale (VAS) and sedation score during and after the operation are recorded.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180602039954N1**
Registration date: **2019-03-10, 1397/12/19**
Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**
Update count: **0**

Registration date
2019-03-10, 1397/12/19

Registrant information
Name
Fatemeh Moftakhar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3338 3372
Email address
goosheh-m@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparsion of the effect of dexmedetomidine and bupivacaine with morphine and bupivacaine on block quality in leg fracture surgeries under epidural anesthesia

Public title
Comparsion of the effect of dexmedetomidine with morphine in surgeries under epidural anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18-60 years old with anesthesia risk ASA I, II

Exclusion criteria:
Lack of satisfaction with epidural blocking Patients dependent on any psychiatric drug Patients with localized infection at the site of the epidural block Patients who had an allergy to the study drugs. Patients with neurological and neuro-macular diseases and psychologists Patients with coagulation disorder Patients who require an analgesic drug during surgery. Patients who fail their epidural block and were under general anesthesia Pregnant women

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization with a random number table is that envelopes are prepared and printed by a member of the research team and random numbers with the help of the Randomaize.com site, and will be embedded in the envelope, and the person will sign the consent form if they wish. Remove an envelope and then open it and enter the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients, responsible for collecting data, data analyzer

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
No 9-Edalat Building-West 12th ST-Kian Abad

City
Ahvaz

Province
Khouzestan

Postal code
6155736793

Approval date
2018-02-18, 1396/11/29

Ethics committee reference number
ir.ajums.rec.1396.938

Health conditions studied

1

Description of health condition studied
Leg fracture

ICD-10 code
S82.8

ICD-10 code description
Other fractures of lower leg

Primary outcomes

1

Description
Block Epidural Quality

Timepoint
Epidural block every two minutes until the sensory level reaches T12, then every 15 minutes; motion block every 5 minutes to bromage 3 times every 30 minutes; Sedation Score every 30 minutes; VAS Score every 30 minutes; Bp, HR; Sat O2 every 5 minutes to half an hour every 15 minutes

Method of measurement
Sensory block with cold swab; Motion block with Bromage scale; Postoperative pain using VAS score; Sedation using Ramsay Scale method.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: consisted of patients who received 12 ml of 0.5% bupivacaine hydrochloride plus dexmedetomidine 1µg/kg (B+D).
Category
Treatment - Other

2

Description
Intervention group2: consisted of patients who received 12 ml of 0.5% bupivacaine hydrochloride plus morphine 2mg/kg (B+M).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Gousheh
Street address
Azadegan Avenue
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3222 2922
Email
goosheh-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badawi
Street address
Deputy of research and technology, Jundishapur University of Medical Sciences, Golestan St
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Phone
+98 61 3336 2414
Fax
+98 61 3336 1544
Email
itc@ajums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Reza Gooshe
Position
Assistant Professor of Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Azadegan Ave,Imam Khomeini Hospital
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3311
Email
Goosheh-m@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh Moftakhar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology

Street address
No:9-Edalat building-West12th St-Kian abad
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Phone
+98 61 3338 3372
Fax
Email
goosheh-m@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh Moftakhar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No:9-edalat building-West12th St-Kian abad
City
Ahvaz
Province
Khouzestan
Postal code
1579461357
Phone
+98 61 3338 3372
Fax
Email
goosheh-m@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Documentation of study, Documentation used in the study, Collected data files, Participants' data after unidentifiable person profile
When the data will become available and for how long
Access to documentation and data are possible at the end of 2019.
To whom data/document is available
Academic researchers, Anesthesiologists, Anesthetic technicians
Under which criteria data/document could be used
Use in the process of treatment in the operating room and processes related to anesthesia
From where data/document is obtainable
Deputy of Research and Technology, Jundishapur University of Medical sciences
What processes are involved for a request to access data/document
Applicant can access documentation by the written request at the end of 2019.
Comments