Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the effect of Dexmedetomidine and Ketamin and Pethidine on prevention of shivering during spinal anesthesia

Protocol summary

Study aim
Comparison of the effects of Dexmedmoedine, Peptidine and Ketamine on shivering during operation in spinal anesthesia

Design
Clinical trial with control group, with parallel groups, double blinded.

Settings and conduct
The medications were previously prepared by an anesthetist in 10cc syringes labeled A, B, C, D and injected by anesthesiologist by an infusion pump in about 10 minutes. Then the patient was placed in a sitting position, and the space between the vertebrae Either L3-L4 or L4-L5 was injected with quinck needle 25 in Median 2 cc bupivacaine 0.5% Hyperbaric in subarakivide space. The patient was then placed in a sleep state and oxygen was given to the patient at 2 liters per minute. The ambient temperature was 23 ° C. After the block was stabilized, a T8-T10 surgical operation started.

Participants/Inclusion and exclusion criteria
Patients aged 18-45 years with ASA class, one and two candidates for elective orthopedic surgery under spinal anesthesia in the operating room of Shahid Mohammadi Bandar Abbas hospital in 1396-1396.

Intervention groups
The first group received ketamine 0.5 mg/kg, and the second group received pethidine 0.5 mg/kg and the third group received dimethomidine 0.5 microgram/kg and the control group received normal intravenous 5 min before subaracneid block.

Main outcome variables
Degree of shivering

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170101031697N3**
Registration date: **2019-07-27, 1398/05/05**
Registration timing: **retrospective**

Last update: **2019-07-27, 1398/05/05**
Update count: **0**

Registration date
2019-07-27, 1398/05/05

Registrant information

Name
Afshin Parvizpanah

Name of organization / entity
Hormozgan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 76 3333 6625

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-03-20, 1395/01/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2016-03-21, 1395/01/02

Actual recruitment end date
2018-02-09, 1396/11/20

Trial completion date
2018-02-21, 1396/12/02

Scientific title
Comparison the effect of Dexmedetomidine and Ketamin and Pethidine on prevention of shivering during spinal anesthesia

Public title
Comparision the effect of Dexmedetomidine and Ketamin and Pethidin on prevention of shivering during spinal anaesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA grade one and two who were candidates for elective orthopedic surgery under spinal anesthesia.
Exclusion criteria:
Those who do not agree to prescribe spinal anesthesia. Provisions for the prescription of spinal anesthesia are prohibited. Patients who are allergic to medications in the study. The patient should be in urgent cases. Patients who have drug addiction. Patients who fail in the nerve block.
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
After identifying the patients, patients were randomly assigned to the study groups. Randomization was carried out in a sub-unit using statistical software.
Blinding (investigator's opinion)
Double blinded
Blinding description
The pump syringes were prepared by an expert in the anesthetic room and the assistant did not know its content.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Bandar Abbas University of Medical Sciences
Street address
Anesthesiology Research Center, Shahid Mohammadi Hospital, Islamic Republic Blvd.
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2017-09-19, 1396/06/28
Ethics committee reference number
HUMS.REC.1395.006

Health conditions studied

1

Description of health condition studied
Effect of Ketamine and Pethidine and Dexmedmotidine on preventing chills during surgery during spinal anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intraoperative shivering during spinal anesthesia
Timepoint
Every 5 minutes to 20 minutes, and then every 10 minutes to 70 minutes, shivering was recorded by an anesthetic expert in a patient's questionnaire.
Method of measurement
According to Clinical Obstetrician Anesthesiologist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ketamine 0.5 mg/kg
Category
Treatment - Drugs

2

Description
Intervention group: Pethidine 0.5 mg/kg
Category
Treatment - Drugs

3

Description
Intervention group: Dexmedetomidine 0.5 micrograms

per kilogram

Category

Treatment - Drugs

4

Description

Control group: Normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohamadi hospital, Bandar Abbas;IRAN

Full name of responsible person

Said Kashani

Street address

Islamic Republic Of Blvd , Shahid Mohammadi Hospital , Bandar Abbas Town , Research Center , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Street address

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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

Said Kashani

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not 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
SPSS file
When the data will become available and for how long
5/17/2019
To whom data/document is available
Researchers and referees
Under which criteria data/document could be used
Obtaining a written permit and mentioning the name in the sources
From where data/document is obtainable
Dr. Saeed Kashani Sdkashani486@gmail.com
What processes are involved for a request to access data/document
Email your request.
Comments