# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**
+98 76 3333 6625

**Email address**
afshin.parvizpanah@hums.ac.ir

**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
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919915519
**Phone**
+98 76 3334 5009
**Email**
Sdkashani486@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Said Kashani
**Street address**
Islamic Republic Blvd , Center for Research Vice , Shahid Mohammadi Hospital , Bandar Abbas Town ,Islamic Republic of Iran
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919915519
**Phone**
+98 76 3334 5009
**Email**
Sdkashani486@gmail.com
**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**
Islamic Republic Blvd , Department of Anesthesiology , Shahid Mohammadi Hospital , Bandar Abbas Town , Islamic Republic of Iran
**City**
Bandar Abbas
**Province**
Hormozgan
**Postal code**
7919915519
**Phone**
+98 76 3334 5009
**Email**
Sdkashani486@gmail.com

## Person responsible for scientific 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**
Islamic Republic Blvd , Department of Anesthesiology , Shahid Mohammadi Hospital , Bandar Abbas Town , Islamic Republic of Iran
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**Email**
Sdkashani486@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Bandare-abbas University of Medical Sciences
**Full name of responsible person**
Said Kashani
**Position**
Anesthesiologist
**Latest degree**
Specialist
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Islamic Republic Blvd , Department of Anesthesiology , Shahid Mohammadi Hospital , Bandar Abbas Town , Islamic Republic of Iran
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**Email**
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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**