# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The Prophylactic effect of ketamine and dexmedetomidine on shivering in patients undergoing inguinal hernia surgery under spinal anesthesia.

## Protocol summary

**Study aim**

Determination of the prophylactic effect of ketamine and dexmedotomedine on shivering of patients undergoing inguinal hernia by spinal anesthesia

**Design**

It will be a non-randomized clinical trial in Phase 3. Blinding will not be performed. Patients will be selected in three groups of 50 at Fatemi Hospital of Ardabil.

**Settings and conduct**

Shivering severity will be determined using BSAS 23 trained by anesthesia technician. During surgery, patients' hemodynamic symptoms will be charted. Shivering will be registered in 4 steps: The moment the patient entering to recovery room, 15 minutes later, 30 minutes later, 45 minutes later.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Candidate herniorrhaphy with spinal anesthesia, consent for inclusion, 18-65 years old
Exclusion criteria: history of drug sensitivity, history of peptic ulcer, systemic infection or immunodeficiency, history of use of monoamine oxidase inhibitor drugs, untreated hypothyroidism, benign prostatic hypertrophy, urinary stenosis and congenital hemorrhagic diseases.

**Intervention groups**

Samples will be divided into three groups, dexmedetomidine and ketamine and the control groups. The first group (ketamine recipients): 50 patients receiving 0.3 mg / kg of diluted ketamine in normal saline with a total volume of 5 ml syringe (injected immediately after spinal anesthesia), dexmedetomidine group: 50 patients containing 1 µg For each kg of body weight diluted dexmedetomidine in normal saline with a total volume of 5 ml syringe (injected immediately after spinal anesthesia). Control group will receive only normal saline. These 3 syringes will be identical in color (the content of all 3 syringes is colorless) and volume (all 3 syringes contain 5 ml of liquid).

**Main outcome variables**

Shivering

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190930044937N1**
Registration date: **2019-10-20, 1398/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**
Update count: **0**

**Registration date**

2019-10-20, 1398/07/28

**Registrant information**

**Name**

Vahid Adiban

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 45 3323 0739

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-06-22, 1398/04/01

**Expected recruitment end date**

2020-03-19, 1398/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Prophylactic effect of ketamine and dexmedetomidine on shivering in patients undergoing inguinal hernia surgery under spinal anesthesia.

**Public title**
Preventive role of ketamine and dexmedetomidine on control of shivering in patients undergoing hernia surgery by spinal anesthesia
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Candidates for inguinal hernias. No life-threatening illness
**Exclusion criteria:**
Weight over 100 kg
**Age**
From **18 years** old to **65 years** old
**Gender**
Male

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **150**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Ardabil University of Medical Sciences
**Street address**
No. 1, Moallem Ave
**City**
Ardabil
**Province**
Ardabil
**Postal code**
5613843793
**Approval date**
2019-07-22, 1398/04/31
**Ethics committee reference number**
IR.ARUMS.REC.1398.182

## Health conditions studied

**1**

**Description of health condition studied**
Inguinal hernia
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Shivering
**Timepoint**
After surgery at the beginning of recovery, 15 minutes, 30 minutes and 45 minutes
**Method of measurement**
BSAS 23 measured by trained anesthesia technician.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: Ketamine recipients consisting of 50 patients receiving 0.3 mg / kg of diluted ketamine in normal saline with total syringe volume of 5 ml (injected immediately after spinal anesthesia).
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group 2: Dexmedetomidine group: 50 patients will receive 1mg / kg of diluted dexmedetomidine in normal saline with total volume of 5 ml syringe (injection immediately after spinal anesthesia).
**Category**
Treatment - Drugs

**3**

**Description**
Control group: 50 patients will receive normal saline only. These 3 syringes will be identical in color (the content of all 3 syringes is colorless) and volume (all 3 syringes contain 5 ml of liquid).
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Fatemi hospital

**Full name of responsible person**
Pedram Poshtareh

**Street address**
No. 1, Emam Khomeyni Ave

**City**
Ardabil

**Province**
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**Postal code**
5613843778

**Phone**
+98 45 3323 0739

**Email**
meisamfooladi@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Ardabil University of Medical Sciences

**Full name of responsible person**
Parvaneh Naftchi

**Street address**
No. 1, Moallem Ave

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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**
Ardabil 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**
Ardabil University of Medical Sciences

**Full name of responsible person**
Vahid Adiban

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ardabil University of Medical Sciences

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Vahid Adiban

**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Vahid Adiban

**Position**
Assistant Professor

**Latest degree**
Specialist
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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**
Undecided - It is not yet known if there will be 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**
Not applicable
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
The questionnaires will be made available anonymously and with a file number.
**When the data will become available and for how long**
After completing the study
**To whom data/document is available**
University professors
**Under which criteria data/document could be used**
In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.
**From where data/document is obtainable**
Contact Dr. Vahid Adiban.
**What processes are involved for a request to access data/document**
Information is available after contacting Dr. Vahid Adiban and University approval
**Comments**