

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 dexmedetomidine 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

p.poshtareh@arums.ac.ir

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

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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

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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

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Full name of responsible person

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Position

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Latest degree

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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

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