

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of intravenous and spinal dexmedetomidine on the quality of spinal anesthesia in patients with inguinal hernia

#### Protocol summary

##### Study aim

Comparison of the effect of intravenous and spinal dexmedetomidine on the quality of spinal anesthesia in patients with inguinal hernia

##### Design

A clinical trial without a parallel control group, do not blind, randomized

##### Settings and conduct

The study was conducted at Shahid Mohammadi Hospital in Bandar Abbas. After obtaining written consent from all patients and after entering the operating room and being placed on the intravenous line of surgery with Angiocut No. 18, non-dominant patients were embedded and after connecting standard monitoring including NIBP (non-invasive blood pressure cuff), pulse oximetry and ECG symptoms The basic vitality of all of them is measured and recorded. All patients receive a balance of 10 ml/kg of saline before performing the block.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with ASA I, II undergo inguinal hernia surgery; Exclusion criteria: Spinal anesthesia contraindication; sensitivity to anesthetic; Patients with addiction or with a history of chronic drug abuse or analgesia; Patients with heart block or unstable cardiovascular status; Patients receiving steroids and agonists; Patients with liver, kidney problems, adrenal and neuromuscular disorders, and diabetic patients; Patients with blockage failure who require medication or induction of general anesthesia; Patients receiving agonist a2

##### Intervention groups

Patients are divided into two groups. Patients in group I receive dexmedetomidine with normal saline and patients in group II receive normal saline

##### Main outcome variables

The severity of the pain; maximal sensory block; Maximum level of motion block; block initiation rate up to T10; sensory block recovery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171030037093N23**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

##### Registration date

2019-10-28, 1398/08/06

##### Registrant information

##### Name

Sadra Ansaripour

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3650 3487

##### Email address

st\_ansari.s@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-21, 1398/06/30

##### Expected recruitment end date

2020-09-20, 1399/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of intravenous and spinal dexmedetomidine on the quality of spinal anesthesia in patients with inguinal hernia

## Public title

Comparison of the effect of intravenous and spinal dexmedetomidine on the quality of spinal anesthesia in patients with inguinal hernia

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 18 to 70 years old Patient with ASA I, II undergo inguinal hernia surgery

### Exclusion criteria:

Patients with ASA greater than or equal to III spinal anesthesia contraindication (Coagulation problems, increased ICP, sepsis, infection) Patients with potential sensitivity to anesthetic or dexmedetomidine Patient with underlying neurological defect Patients with addiction or with a history of chronic drug abuse or analgesia Patients with heart block or unstable cardiovascular status Patients receiving steroids and agonists Patients with liver, kidney problems, adrenal and neuromuscular disorders, and diabetic patients Patients with blockage failure who require medication or induction of general anesthesia. Patients receiving agonist a2

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sample was randomly divided into two groups. Each envelope containing one of the two labels A and B represented one of the intervention groups.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

#### Street address

Deputy of research and technology, the Supreme Prophet's Hospital, Bandar Abbas

#### City

Bandar Abbas

#### Province

Hormozgan

#### Postal code

9791991551

#### Approval date

2017-11-13, 1396/08/22

#### Ethics committee reference number

IR.HUMS.REC.1396.37

## Health conditions studied

## 1

### Description of health condition studied

inguinal hernia

### ICD-10 code

K40

### ICD-10 code description

Inguinal hernia

## Primary outcomes

## 1

### Description

Severity of pain

### Timepoint

After surgery

### Method of measurement

According to VAS

## 2

### Description

Maximum level of sensory block

### Timepoint

During surgery every ten minutes

### Method of measurement

Through the cold feeling of cotton alcohol

## 3

### Description

block initiation rate up to T10

### Timepoint

Once before surgery

### Method of measurement

observation

## 4

### Description

sensory block recovery

**Timepoint**

Once after surgery

**Method of measurement**

observation

**5****Description**

Maximum level of motion block

**Timepoint**

During surgery every ten minutes

**Method of measurement**

Computing

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group: 1 µg / kg receive dexmedetomidine with normal saline in a total volume of 20 ml at the same time 10 minutes before the intravenous block.

**Category**

Treatment - Drugs

**2****Description**

Second intervention group: 20 ml of normal saline are pumped through the syringe of the pump for 10 minutes before the venous block

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Mohammadi Hospital of Bandar Abbas

**Full name of responsible person**

Hashem Jarineshin

**Street address**

Boulevard of the Islamic Republic of Iran, Bandar Abbas, Shahid Mohammadi Hospital

**City**

Bandar Abbas

**Province**

Hormozgan

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**Phone**

+98 76 3334 7000

**Email**

Anrc.hums@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Abdul Azim Nejati Zadeh

**Street address**

Deputy of research and technology, East Side, Bandar Abbas Hospital, Bandar Abbas

**City**

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**Province**

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**Phone**

+98 71 3333 5794

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azimnejate@yahoo.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**

Iran University of Medical Sciences

**Full name of responsible person**

Hashem Jarineshin

**Position**

Associate Professor of Anesthesiology

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Department of Anesthesiology, Shahid Mohammadi Hospital

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**Postal code**

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**Phone**

+98 917 361 3464

**Email**

shmh@hums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Hashem Jarineshin

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Information about the main outcome can be shared.

**When the data will become available and for how long**

Start the access period 4 months after publishing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

Use data to complete clinical trial studies

**From where data/document is obtainable**

Shahid mohammadi hospital

**What processes are involved for a request to access data/document**

After the investigation of researcher request and presentation of required documents will be accessible.

**Comments**