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; ensitivity 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

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Iran (Islamic Republic of)

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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

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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

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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

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

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Person responsible for updating data

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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