

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

study the effects and complications of bilateral spinal anesthesia with the unilateral spinal anesthesia in patients suffering unilateral inguinal hernia

Protocol summary

Study aim

Study the effects and complications of bilateral spinal anesthesia with the unilateral spinal anesthesia in patients suffering unilateral inguinal hernia

Design

A clinical trial without control group, with parallel, unblinded, randomized groups

Settings and conduct

A peripheral vein No. 18 is inserted per patient and 10 cc/kg of Ringer patient weight is injected. Then, according to the randomization table, each patient enters group B (bilateral spinal anesthesia) or group U (unilateral spinal anesthesia). In group B, patients were placed in a sitting position, after complete sterilization, with a Quincke 25G needle pierced through the L4-L5 intervertebral space after transcutaneous cerebrospinal fluid flow, 2.5 cc of bupivacaine. 0.5% isobar is injected at 1 cc for 30 seconds and is restored to the supine position immediately after the injection is completed. In group U, patients were placed supine, with the lower hernia positioned, after complete sterilization, with the Quincke 25G needle pierced through the L4-L5 intervertebral needle after clear fluid flow. The spinal cord, 1.5 cc of 0.5% isobar bupivacaine, is injected at 1 cc for 30 seconds, remaining in the same position for 15 minutes and then resting on the supine position.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with a unilateral inguinal hernia; Patients with grade 1 and two ASA; Exclusion criteria: Patient dissatisfaction with spinal anesthesia; Coagulopathy; Sensitivity to topical anesthetics; Cerebrospinal cord injury; An ulcer or infection in the area of anesthesia; Lack of proper anesthesia for any reason

Intervention groups

We have two intervention groups. The first group has bilateral spinal anesthesia and the second group has

unilateral spinal anesthesia.

Main outcome variables

Blood pressure, heart rate, oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N19**

Registration date: **2019-09-30, 1398/07/08**

Registration timing: **prospective**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Sadra Ansari pour

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

2019-10-23, 1398/08/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
study the effects and complications of bilateral spinal anesthesia with the unilateral spinal anesthesia in patients suffering unilateral inguinal hernia

Public title
study the effects and complications of bilateral spinal anesthesia with the unilateral spinal anesthesia in patients suffering unilateral inguinal hernia

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with unilateral inguinal hernia Patients with grade 1 and two ASA
Exclusion criteria:
 Patient dissatisfaction with spinal anesthesia
 Coagulopathy Sensitivity to topical anesthetics
 Cerebrospinal cord injury An ulcer or infection in the area of anesthesia Lack of proper anesthesia for any reason

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The study sample was randomly divided into two groups of 50 people, each by selective envelopes. Thus, each envelope containing one of the three U and B labels represented one of the 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
2018-05-13, 1397/02/23

Ethics committee reference number
IR.HUMS.REC.1397.037

Health conditions studied

1

Description of health condition studied

unilateral inguinal hernia

ICD-10 code

K40.4

ICD-10 code description

Unilateral inguinal hernia, with gangrene

Primary outcomes

1

Description

Blood pressure

Timepoint

Before anesthesia and immediately after injection of anesthesia and after 5, 10 and 15 minutes

Method of measurement

measurement

2

Description

heart rate

Timepoint

Before anesthesia and immediately after injection of anesthesia and after 5, 10 and 15 minutes

Method of measurement

measurement

3

Description

oxygen saturation

Timepoint

Before anesthesia and immediately after injection of anesthesia and after 5, 10 and 15 minutes

Method of measurement

measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, bilateral spinal anesthesia is performed and the patients are in a sitting position, after complete sterilization, with the Quincke 25G needle pierced through the L4-L5 intervertebral space after clear flow. The cerebrospinal fluid, 2.5 cc of 0.5% isobar bupivacaine, is injected at 1 cc for 30 seconds and is restored to the supine position immediately after completion of the injection.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, unilateral spinal anesthesia is performed. Patients were placed in a supine position with the lower hernia positioned, after complete sterilization, with the Quincke 25G needle pierced through the L4-L5 intervertebral space after a clear flow of cerebrospinal fluid, 1.5 cc of 0.5% isobar bupivacaine is injected at 1 cc for 30 seconds and remains in the same position for 15 minutes after completion of the patient's injection and then rests on the supine position.

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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Bandar Abbas

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+98 76 3334 7000

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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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9791991551

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+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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+98 917 361 3464

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shmh@hums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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Person responsible for updating data

Contact

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

Comments