Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Study aim
Study the effects and complications of bilateral spinal anesthsia 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 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
2019-10-23, 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 anesthsia with the unilateral spinal anesthesia in patients suffering unilateral inguinal hernia

Public title

study the effects and complications of bilateral spinal anesthsia 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

City
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

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
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

Phone
+98 71 3333 5794

Email
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

City
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

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

Position
Associate Professor of Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology, Shahid Mohammadi Hospital

City
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

Phone
+98 917 361 3464

Email
shmh@hums.ac.ir

Person responsible for updating data

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

City
Bandar Abbas

Province
Hormozgan

Postal code
9791991551

Phone
+98 917 361 3464

Email
shmh@hums.ac.ir

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