

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of hemodynamic index and duration of effect of two drugs, bupivacaine and ropivacaine during spinal and epidural analgesia in orthopedic lower extremity surgery and umbilical cord surgery (T8 level)

Protocol summary

Study aim

Comparison of hemodynamic index and duration of effect of two drugs, bupivacaine and ropivacaine during spinal and epidural analgesia in orthopedic surgery of the lower extremity and umbilicus (T8 level)

Design

Controlled clinical trial, randomized, double-blind, on 80 patients, randomized based on random function

Settings and conduct

Imam Reza Hospital in Birjand - 1398

Participants/Inclusion and exclusion criteria

Entry requirements: Patients referred to Imam Reza Hospital who underwent lower limb orthopedics and umbilical cord surgery without underlying disease, using a tourniquet, without bleeding and operation time less than 1 hour and 45 minutes Exit conditions: People with any underlying disease, people who have a ban on spinal anesthesia (such as coagulation disorders, infection at the site of anesthesia, hypovolemia and unwillingness to anesthetize)

Intervention groups

The first group (30 people) will receive 20 ml of ropivacaine the second group (30 people) will receive 20 ml of bupivacaine.

Main outcome variables

Systolic pressure Diastolic pressure heart beat Create sensory blocks Length of effect of two drugs side effects Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210218050400N1**

Registration date: **2021-03-04, 1399/12/14**

Registration timing: **prospective**

Last update: **2021-03-04, 1399/12/14**

Update count: **0**

Registration date

2021-03-04, 1399/12/14

Registrant information

Name

habibe momeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3290 4004

Email address

habibe.momeni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic index and duration of effect of two drugs, bupivacaine and ropivacaine during spinal and epidural analgesia in orthopedic lower extremity surgery and umbilical cord surgery (T8 level)

Public title

Comparison of hemodynamic index and duration of effect of two drugs, bupivacaine and ropivacaine during spinal

and epidural analgesia in orthopedic lower extremity surgery and umbilical cord surgery (T8 level)

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Patients referred to Imam Reza Hospital who underwent lower limb orthopedics and umbilical cord surgery without underlying disease, using a tourniquet without bleeding and operation time less than 1 hour and 45 minutes
Exclusion criteria:
People with any underlying disease, people who have a ban on spinal anesthesia (such as coagulation disorders, infection at the site of anesthesia and unwillingness to anesthetize hypovolemia)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method will be simple random so that 60 cards with two different colors, each color will represent a group, will be placed in a box. After entering the operating room, the patient will first check the entry criteria and if Being the entry criterion, a card will be pulled out of the box and will be placed in the desired group (B or A) according to the color of the card.

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
Vice Chancellor for Research, Birjand University of Medical Sciences
Street address
Ghafari
City
Birjand
Province

South Khorasan
Postal code
9771648719
Approval date
2021-02-15, 1399/11/27
Ethics committee reference number
IR.BUMS.REC.1399.510

Health conditions studied

1
Description of health condition studied
Spinal T8 level
ICD-10 code
-
ICD-10 code description

2
Description of health condition studied
T8 level analgesic epidural
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
blood pressure
Timepoint
Every 5 minutes to 30 minutes after injection and then every 15 minutes until the end of the operation.
Method of measurement
Blood pressure monitor

2
Description
Blood oxygen level
Timepoint
Every 5 minutes to 30 minutes after injection and then every 15 minutes until the end of the operation
Method of measurement
Pulse oximetry

3
Description
Duration of anesthesia
Timepoint
Every 5 minutes to 30 minutes after injection and then every 15 minutes until the end of the operation
Method of measurement
Based on sensory level

4
Description
Intensity of sensory block
Timepoint

Every 5 minutes to 30 minutes after injection and then every 15 minutes until the end of the operation

Method of measurement

Based on sensory level

5

Description

The effectiveness of drugs

Timepoint

Intervals of 5 minutes for the first 30 minutes after injection

Method of measurement

Using 100 mm analog pain scores (VAPS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 30 people in intervention group 1 will be injected 20 ml of ropivacaine into the epidural space once before the operation using a 3 cm multifunctional epidural catheter.

Category

Treatment - Drugs

2

Description

Intervention group 2: 30 people in intervention group 2 will be injected with 20 cm 20 ml bupivacaine into the epidural space once before the operation using a multifunctional epidural catheter.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Birjand

Full name of responsible person

Atiye Validad

Street address

Ghafari. Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9771648719

Phone

+98 56 3290 4004

Email

Pooh199069@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Toba Kazemi

Street address

Ghafari, Birjand University of Medical Sciences

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Birjand

Province

South Khorasan

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9771648719

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Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Atiye Validad

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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City

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Postal code

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Phone

+98 915 164 0940

Email

Pooh199069@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Atiye Validad

Position

student

Latest degree

Medical doctor

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Person responsible for updating data

Contact

Name of organization / entity

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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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

After submitting the proposal and collecting data and analyzing the results, the final report will be registered and the results will be published as an article.

When the data will become available and for how long

-

To whom data/document is available

General and field specialists

Under which criteria data/document could be used

After the publication of the article

From where data/document is obtainable

Corresponding

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

Submit proposal, collect data, submit final report and publish article

Comments