Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison efficacy of Ropivacaine versus Bupivacaine in Spinal Anesthesia in Percutaneous Nephrolithotomy

Protocol summary

Study aim
Comparison of the efficacy of ropivacaine and bupivacaine in bioshospinal surgery for kidney stone removal surgery

Design
This study will be performed by randomized double-blind clinical trial with factorial groups on 100 patients referred to Peymaniyeh Hospital in Jahrom who are undergoing pcnl surgery. Patients participating in the study will be divided into two groups by coin toss.

Settings and conduct
Patients referred to Jahrom's Peymaniyeh Hospital, who will undergo pcnl surgery, will enter the study. Patients participating in the study will be divided into two groups, Bupivacaine and Rupivacaine, by coin toss. The study participant, the researcher, and the data collector will be unaware of the type of medication being taken.

Participants/Inclusion and exclusion criteria
All patients referred to Peymaniyeh Hospital in Jahrom who have undergone PCNL surgery and are satisfied to participate in the study and do not have the criteria to leave the study.

Intervention groups
Intervention group1: 15 mg of bupivacaine is administered intrathecally. Intervention group2: 15 mg of ropivacaine is administered intrathecally.

Main outcome variables
Pain, movement, hemodynamics, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130926014779N5**
Registration date: **2020-06-13, 1399/03/24**
Registration timing: **registered_while_recruiting**
Last update: **2020-06-13, 1399/03/24**
Update count: **0**

Registration date
2020-06-13, 1399/03/24

Registrant information

Name
Navid Kalani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 5426 4192

Email address
k.navid@jums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-31, 1398/10/10

Expected recruitment end date
2020-09-26, 1399/07/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison efficacy of Ropivacaine versus Bupivacaine in Spinal Anesthesia in Percutaneous Nephrolithotomy

Public title
Comparison efficacy of Ropivacaine versus Bupivacaine in Spinal Anesthesia in Percutaneous Nephrolithotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodynamic stability Having the desired ASA (Classes 1 and 2 were considered the criteria for entering the study)

Exclusion criteria:

People who need medication or action other than routine care during surgery to relieve complications and reduce pain. Chronic and cancerous pains Concomitant Disorders High intracranial pressure

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients participating in the present study were divided into two groups by coin toss.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding in the present study, a double-blind method is used in a way that (1) the person who will review the results and (2) the person who performs the injections are unaware of which patients have received dexmedetomidine ،fentanil and bupivacaine alone

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Jahrom University of Medical Sciences

Street address

School of medicine, Motahhari Blvd, Jahrom

City

Jahrom

Province

Fars

Postal code

716775243

Approval date

2019-11-08, 1398/08/17

Ethics committee reference number

IR.JUMS.REC.1398.043

Health conditions studied

1

Description of health condition studied

kidney stone

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Method of measurement

Visual Analogue Scale

2

Description

nausea Vomiting

Timepoint

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Method of measurement

questionnaire

3

Description

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Timepoint

bromage scale

Method of measurement

bromage scale

Secondary outcomes

1

Description

Hemodynamics

Timepoint

Before the spinal, after the spinal and during the change of position of the patient and then every 15 minutes to the first hour and also during the entry into recovery and when leaving the recovery and finally three and six hours after the operation

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group1: 15 mg of bupivacaine is administered intrathecally.

Category

Treatment - Drugs

2

Description

Intervention group2: 15 mg of ropivacaine is administered intrathecally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Peymanieh Hospital, Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahhari Boulevard, Peymaniyeh Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

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Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

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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

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

navid kalani

Position

Research employee

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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