

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 Ropivacaine, 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)

Phone

+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

Solh Ju Kavos

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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 scientific inquiries

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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