

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the efficacy of 0.5% bupivacaine with and without fentanyl in spinal anesthesia of patients with proximal ureteral stones under transureteral lithotripsy (TUL)

Protocol summary

Study aim

Determination of the efficacy of 0.5% bupivacaine with the addition of fentanyl in spinal anesthesia of patients with proximal ureteral stones under transureteral lithotripsy (TUL)

Design

Phase 3 clinical trial with control group, with parallel groups, double-blind, randomized by block randomization method with blocks of size 4 with a ratio of 1 to 1 (as two groups A and B), with a sample size of 54 patients

Settings and conduct

The study will be performed in the urology operating room of Razi Hospital in Rasht. The study will be double blind in which neither the patient nor the researcher responsible for completing the questionnaires is aware of the combination of anesthetic drug allocated to surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 15 years and under 65 years; Patients with ASA (American Society of Anesthesiologists) Class I and II Exclusion criteria: History of chronic pain; Patients with multiple trauma; Long-term use of painkillers; Drug abuse; History of alcohol consumption; Having a prohibition (absolute or partial) for intrathecal injection; Allergies to bupivacaine and fentanyl

Intervention groups

Intervention group: Spinal injection of bupivacaine 10 mg with 0.5 ml fentanyl (25µg)

Main outcome variables

Level of sensory block; Level of movement block; Degree of relaxation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210206050260N1**

Registration date: **2021-04-17, 1400/01/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-17, 1400/01/28**

Update count: **0**

Registration date

2021-04-17, 1400/01/28

Registrant information

Name

Ardalan Akhavan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-05, 1400/01/16

Expected recruitment end date

2021-09-07, 1400/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of 0.5% bupivacaine with and without fentanyl in spinal anesthesia of patients with proximal ureteral stones under transureteral lithotripsy

(TUL)

Public title
The efficacy of bupfentanyl in spinal anesthesia of patients with proximal ureteral stones

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA (American Society of Anesthesiologists) Class I and II
Exclusion criteria:
History of chronic pain Patients with multiple trauma
Long-term use of painkillers Drug abuse History of alcohol consumption Having a prohibition (absolute or partial) for intrathecal injection Allergies to bupivacaine and fentanyl

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with blocks of size 4 with a ratio of 1 to 1 (as two groups A and B) via a online program named sealed envelop/randomisation

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither the patient nor the evaluator is aware of the anesthesia drug combination assigned to the surgery. At the top of the checklist which be completed for each patient, the group type (A or B) will be recorded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Sardar Jangal street

City
Rasht
Province
Guilan
Postal code
41448-95655
Approval date
2021-02-03, 1399/11/15
Ethics committee reference number
IR.GUMS.REC.1399.581

Health conditions studied

1

Description of health condition studied

Spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of sensory block

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

With Pin Prick test

2

Description

Level of movement block

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

With Bromage Scale

3

Description

Degree of relaxation

Timepoint

Every 15 minutes during surgery and recovery

Method of measurement

With Ramsay Score

Secondary outcomes

1

Description

Operative time

Timepoint

At the end of the surgery

Method of measurement

Stopwatch

2

Description

Complications of anesthesia

Timepoint

After surgery, during the period of hospitalization

Method of measurement

Question from the patient, examination

3

Description

The level of pain

Timepoint

After surgery, during the period of hospitalization

Method of measurement

With VAS score

4

Description

Recovery time

Timepoint

From the beginning of entering the recovery to the time of leaving it

Method of measurement

Stopwatch

5

Description

Blood pressure

Timepoint

Immediately after spinal injection every 2 minutes to 10 minutes and then every 5 minutes until the end of surgery then repeatedly in the recovery and the ward

Method of measurement

By intraoperative monitoring and postoperative sphygmomanometer

6

Description

Heartbeat

Timepoint

Every 5 minutes during the operation

Method of measurement

By intraoperative monitoring

Intervention groups

1

Description

Intervention group: Spinal injection of bupivacaine 10 mg with 0.5 ml fentanyl (25µg)

Category

Treatment - Drugs

2

Description

Control group: Spinal injection of bupivacaine 10 mg with

0.5 ml of normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Ardalan Akhavan

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Sardar-e-Jangal street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

Siavash Falahatkar

Street address

Sardar-e-Jangal Avenue

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Rasht

Province

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urc@gums.ac.ir

Grant name

10506

Grant code / Reference number

32

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

Yes

Title of funding source

Urology Research Center, Guilan 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

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Hossein Khoshrang

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Contact**Name of organization / entity**

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

Samaneh Esmaeili

Position

Non-faculty researcher

Latest degree

Master

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Ardalan Akhavan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Sardar-e-Jangal Ave.

City

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Province

Guilan

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

No - There is not a plan to make this available