Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 13 3352 5259

Email address
ardalan.akhavan@gmail.com

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
Street address
Sardar-e-Jangal street
City
Rasht
Province
Guilan
Postal code
41448-95655
Phone
+98 13 3352 5259
Email
ardalan.akhavan@gmail.com

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
City
Rasht
Province
Guilan
Postal code
41448-95655
Phone
+98 13 3352 5259
Email
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

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
Street address
Sardar-e-Jangal Ave.
City
Rasht
Province
Guilan
Postal code
41448-95655
Phone
+98 13 3352 5259
Email
hkhoshrang@yahoo.com

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
Street address
Sardar-e-Jangal Ave.
City
Rasht
Province
Guilan
Postal code
41448-95655
Phone
+98 13 3352 5259
Email
ardalan.akhavan@gmail.com

Person responsible for updating data

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
Street address
Sardar Jangal St.
City
Rasht
Province
Guilan
Postal code
41448-95655
Phone
+98 13 3352 5259
Email
samaneh_815@yahoo.com

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