Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of erector spinae block and paravertebral block using ropivacaine on pain intensity and need for analgesics after percutaneous nephrolithotomy in patients of Firoozgar Hospital.

Protocol summary

Study aim

Comparison of the effectiveness of muscle plate block and paravertebral block using ropivacaine in reducing postoperative pain and the need for analgesics in nephrolithotomy patients.

Design

This is a randomized clinical trial designed to compare the analgesic effects and opioid consumption reduction of spinal plate block (ESP) versus paravertebral block (PVB) using ropivacaine in patients undergoing nephrolithotomy.

Settings and conduct

This study will be conducted at Firoozgar Hospital, affiliated with Iran University of Medical Sciences. Eligible patients undergoing nephrolithotomy will be recruited after obtaining written informed consent. Randomization will be performed using block randomization via computer software. Standard perioperative care will be provided, and all procedures will follow the study protocol. The research team will oversee the study conduct, and patient data will be kept confidential.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients aged 20 to 65 - BMI less than 30 - No drug addiction Exclusion criteria: - Drug addiction - BMI> 30 - Under 20 over 65

Intervention groups

Intervention group 1: Patients will receive an extraspinal block (ESP) using 20 ml of 0.25% ropivacaine under ultrasound guidance before nephrolithotomy surgery. Intervention group 2: Patients will receive a paravertebral block (PVB) using 20 ml of 0.25% ropivacaine under ultrasound guidance before nephrolithotomy surgery.

Main outcome variables

Postoperative pain intensity assessed using the Visual Analog Scale (VAS) at multiple timepoints (e.g., 1, 6, 12, 24 hours after surgery) - Total analgesic consumption within the first 24 hours postoperatively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251028067791N1**
Registration date: **2025-11-13, 1404/08/22**
Registration timing: **prospective**

Last update: **2025-11-13, 1404/08/22**
Update count: **0**

Registration date

2025-11-13, 1404/08/22

Registrant information

Name

Ahmad shoaib Sahil

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 938 665 2685

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arveensahel120@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of erector spinae block and paravertebral block using ropivacaine on pain intensity and need for analgesics after percutaneous nephrolithotomy in patients of Firoozgar Hospital.

Public title
Comparison of two type of anesthesia on pain intensity in PCNL surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient's age is between 20 - 65. BMI <30 should be less than Not be addicted to drugs Do not take painkillers 48 hours before the procedure. The duration of the procedure should be less than 3 hours.

Exclusion criteria:
The patient is older than 65 and younger than 20 The patient's BMI is greater than 30. Have a drug addiction If you have taken painkillers 48 hours before the procedure If the procedure lasts more than 3 hours

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **92**
More than 1 sample in each individual
Number of samples in each individual: **4**
Estimating pain at 1, 6, 12, and 24 hours after percutaneous nephrolithotomy using neuromuscular block and paravertebral block combined with ropivacaine.

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to one of the two groups (paravertebral block or quadratus lumborum block) using a random number table (or computer-generated randomization). The allocation will be performed by a person not involved in the intervention or outcome assessment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
"My study is being conducted at a single center and aims to compare the effectiveness of two types of pain blocks in reducing the need for analgesics after nephrolithotomy. Therefore, the study design is single-center and aims to investigate the superiority of one method over the other."

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Research, Faculty of Medicine - Iran University of Medical Sciences

Street address
Vali Asr Square, Shahamati Alley, No. 11, Unit 5

City
Tehran

Province
Tehran

Postal code
1136914151

Approval date
2025-10-25, 1404/08/03

Ethics committee reference number
IR.IUMS.FMD.REC.1404.490

Health conditions studied

1

Description of health condition studied
postoperative pain after nephrolithotomy

ICD-10 code
N20

ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Pain intensity measured by Visual Analog Scale (VAS) at defined postoperative intervals (e.g., 2, 6, 12, 24 hours) - *Total analgesic consumption* (e.g., mg of morphine or equivalent) within the first 24 hours after surgery

Timepoint
At 1, 6, 12, and 24 hours postoperative and cumulative analgesic consumption within 24 hours after surgery

Method of measurement
1: Visual Analog Scale (VAS), a 10-cm scale where 0 indicates no pain and 10 indicates worst imaginable pain.
2:Total amount of analgesic drugs (e.g., morphine equivalents) recorded from patient charts during the first 24 hours postoperatively.

Secondary outcomes

1

Description
1: Patient satisfaction level with pain control 2: Occurrence of complications related to the block (e.g. hypotension, nausea) 3: Time of first request for analgesics 4: Changes in vital signs after the block
Timepoint
at 1, 6, 12, and 24 hour postoperative
Method of measurement
1.Patient satisfaction: Measured using a standardized 5-point Liker scale questionnaire postoperatively. 2.Complications (e.g., hypotension, nausea): Monitored and recorded by clinical observation and chart review.3.Time to first analgesic request: Recorded in hours from end of surgery until the first analgesic demand by patient, via nursing chart. 4.Vital signs: Measured using standard hospital monitoring equipment (blood pressure, heart rate, respiratory rate) and recorded at regular intervals postoperatively.

Intervention groups

1

Description
Intervention group: Ultrasound-guided Erector Spinae Plane Block (ESP block)with Ropivacaine 0.2%, volume 20-30 ml, administered preoperatively at the level of T8-T9 on the side of surgery.
Category
Treatment - Drugs

2

Description
Intervention group: Ultrasound-guided Paravertebral Block with Ropivacaine 0.2%, volume 20-30 ml, administered preoperatively at the level of T10-T11 on the side of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Ahmad shoaib sahil
Street address
Tehran, Kargarshmal Street, between Jeyhoun Street and Jamalzadeh Street, Firoozgar Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
PHD Dr. Sapeeda khoee
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr Robab maghsoudi
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
No - There is not a plan to make this available
Title and more details about the data/document
Title: Data Dictionary for Nephrolithotomy Pain Study
Details: This file includes variable names, labels, and coding information used for analyzing pain scores and analgesic requirements in the study comparing paravertebral and ESP blocks with ropivacaine.
When the data will become available and for how long
the data will become available 6 months after the study completion data and will remain available for 5 years upon reasonable request.
To whom data/document is available
the data will be available to qualified researchers upon reasonable request and after approval by the principal investigator.
Under which criteria data/document could be used
the data my be used for academic, non-commercial research purposes upon formal request, approval by the principal investigator, and signing of a data sharing agreement.
From where data/document is obtainable
data can be obtained by contacting the principal investigator via the provided email address.
What processes are involved for a request to access data/document
interested researchers should submit a formal written request including the purpose and analysis plan. the request will be reviewed by study team or ethics committee, and upon approval, data access will be granted under data-sharing agreements.
Comments
All relevant information regarding the study has been provided in the previous sections.