Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison analgesia of erector spinae plane block under ultrasound guidance and the combination of subfascial and subcutaneous ropivacaine blocks in open kidney donor nephrectomy surgery

Protocol summary

Study aim
Comparing different postoperative analgesia methods after elective open donor nephrectomy

Design
A clinical trial with 3 groups, with parallel groups, double-blinded, randomized, phase 3 on 105 patients.

Settings and conduct
After the approval of the ethics committee and obtaining the consent of the patients, 105 candidates for open nephrectomy for kidney donation at Modarres Hospital who meet the entry criteria will be included in the study. Patients are assigned to one of the three groups by simple randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 70 years who are volunteer kidney donors and candidates for elective open nephrectomy and are in physical status I or II according to the American Society of Anesthesiologists (ASA) classification. Exclusion criteria: Use of anticoagulants, presence of blood or coagulation disorders, history of sensitivity to local anesthetics, or patient refusal to participate in the study.

Intervention groups
At the end of surgery and prior to anesthesia reversal, patients will be randomized into three groups: Group 1 (ESPB): Under ultrasound guidance, an erector spinae plane block (ESPB) will be performed by the anesthesiologist in the flank position, using 20 mL of 0.25% ropivacaine. Group 2 (Surgeon-Administered): Before fascial closure, the surgeon (the same individual for all patients) will administer 10 mL of 0.25% ropivacaine subfascially and 10 mL of 0.25% ropivacaine subcutaneously at the incision site. Group 3 (Control): Patients will receive morphine 0.1 mg/kg for analgesia, without any nerve block.

Main outcome variables
The first time requiring analgesic; pain intensity; number of times requiring injectable analgesic; amount of opioid consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230204057318N9**
Registration date: **2025-07-19, 1404/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-19, 1404/04/28**
Update count: **0**

Registration date
2025-07-19, 1404/04/28

Registrant information

Name
Alireza Shakeri

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-19, 1404/04/28

Expected recruitment end date
2025-10-20, 1404/07/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison analgesia of erector spinae plane block under ultrasound guidance and the combination of subfascial and subcutaneous ropivacaine blocks in open kidney donor nephrectomy surgery

Public title

Comparison of erector spinae and the subfascial-subcutaneous blocks

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Elective open nephrectomy for kidney donor American Society of Anesthesiologists (ASA) physical status classification of I or II

Exclusion criteria:

Anticoagulant agent use Blood abnormality or coagulation disorders Allergy history to local anesthetics Patient refusal

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a simple randomization method will be used using Random Generator software. First, a set of random numbers will be generated, then eligible patients will receive a random number before anesthesia. Based on the assigned number, patients will be assigned to one of three study groups (numbers 1 to 35 were assigned to Group 1, numbers 36 to 70 to Group 2, and numbers 71 to 105 to Group 3).

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant information will be recorded and utilized exclusively using a numerical code to ensure that both their identity and the type of intervention remain unknown. Throughout all stages of data collection, outcome assessment, and statistical analysis, the research team members will only be exposed to these codes and will have no knowledge of the intervention type. (Allocation Concealment) Participants will be unaware of which treatment group they are in. Nevertheless, all treatment methods in the study will be explained to each participant at the beginning when obtaining consent, and the apparent procedures will be identical for all groups, as patients will be under anesthesia during the procedure and the blocks do not create any visual difference for observation. (Blinding) The clinical caregiver (surgeon and anesthesiologist) will only be aware of the type of intervention for the duration of its performance and will have no role in data collection or results analysis after the intervention. The individual responsible for data collection and outcome assessment will only have access to each person’s random code and will be unaware of the group allocation and the type of intervention participants received. The statistical analyst will conduct the data analysis with the coded data, without knowledge of the intervention type, to ensure the blinding process is maintained throughout the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Yaman st., Shahid Chamran Hwy.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-10-08, 1403/07/17

Ethics committee reference number

IR.SBMU.MSP.REC.1403.421

Health conditions studied

1

Description of health condition studied

Pain control after open nephrectomy in donors

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description
First time to analgesic demand
Timepoint
First timepoint for requesting analgesic
Method of measurement
Minutes based on a stopwatch

Secondary outcomes

1

Description
Total postoperative opioid consumption
Timepoint
Once after 24 hours after surgery
Method of measurement
The amount of opioid consumed by patients in the first 24 hours after surgery in milligrams (mg) and reported based on (Morphine Equivalent Dose - MED) from hospital medical records and data recorded in the PCA (Patient-Controlled Analgesia) pump.

2

Description
Postoperative pain
Timepoint
The measurement will be taken postoperatively in the recovery room, and at 6, 12, and 24 hours after surgery.
Method of measurement
Visual analog scale

3

Description
Number of times the patient requested analgesic medication
Timepoint
During the first 24 hours after surgery
Method of measurement
The number of times patients requested analgesic medication during the first 24 hours after surgery will be obtained from medical records.

Intervention groups

1

Description
Intervention Group 1: Erector Spinae (ESPB) Group. After confirming landmarks and the correct injection site (T7–T9 vertebral levels, erector spinae muscle, transverse process), an ultrasound-guided in-plane technique will be performed using a 22G needle. The needle tip will be positioned on the transverse process of the vertebra. A local anesthetic (20 mL of 0.25% ropivacaine) will be injected.
Category
Treatment - Surgery

2

Description
Intervention Group 2: Surgeon-Administered Injection. At the end of the surgery, before closing the fascia, the surgeon (the same individual for all patients) will inject 10 milliliters of 0.25% ropivacaine subfascially and 10 milliliters of 0.25% ropivacaine subcutaneously at the incision site.
Category
Treatment - Surgery

3

Description
In the control group, patients will receive only morphine at a dose of 0.1 mg/kg for pain relief without receiving any nerve block.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres Hospital
Full name of responsible person
Maede Karimian
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Modarres Hospital, Saadat Abad intersection, Yadgar Imam highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Shakeri
Position
Assistant professor
Latest degree
Specialist
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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