# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

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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**

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**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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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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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**

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## Person responsible for updating data

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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