Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Local Lidocaine Infiltration, Intramuscular Morphine, and Placebo for Postoperative Pain Control After Percutaneous Nephrolithotomy (PCNL): A Double-Blind Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the effect of local lidocaine infiltration, intramuscular morphine, and placebo on pain control and reduction of opioid analgesic consumption after PCNL in patients receiving a standard analgesic regimen.

Design

Phase III, double-blind, parallel-group, three-arm (local lidocaine, intramuscular morphine, placebo) randomized controlled trial with 60 patients. Block randomization (block size 6) was performed using SPSS software. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes. All patients received a standard baseline analgesic regimen.

Settings and conduct

Urology Dept., Shahid Beheshti Hosp., Hamadan, Iran. Mar–Sep 2026. Consecutive elective PCNL patients randomized to three groups. Patient, outcome assessor, analyst blinded (double-blind via third-party nurse). Interventions at surgery end; 48h follow-up.nts were followed for 48 hours postoperatively.

Participants/Inclusion and exclusion criteria

Adult patients (≥18 years) of both sexes scheduled for elective standard PCNL with ASA physical status I-III; no chronic opioid use; non-pregnant and non-lactating women. Exclusion criteria: allergy to lidocaine or morphine; coagulopathy; active untreated urinary tract infection (positive culture); severe obesity (BMI ≥40 kg/m²); need for multiple tracts or simultaneous double-J stent; history of open renal surgery or previous PCNL on the same kidney; abnormal renal anatomy; conversion to open surgery or intra-operative emergency; significant bleeding requiring transfusion; need for postoperative ICU admission.

Intervention groups

Group A: 20mL 2% lidocaine (4mg/kg) locally + standard regimen. Group B: 5mg IM morphine + standard regimen. Group C: 20mL normal saline locally + standard regimen

Main outcome variables

VAS score at 6,12,24,48h; total rescue pethidine at 48h; time to first analgesic request.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260428069197N1**
Registration date: **2026-06-28, 1405/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-28, 1405/04/07**
Update count: **0**

Registration date

2026-06-28, 1405/04/07

Registrant information

Name

Reza Shamsollahi

Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-11-21, 1405/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Local Lidocaine Infiltration, Intramuscular Morphine, and Placebo for Postoperative Pain Control After Percutaneous Nephrolithotomy (PCNL): A Double-Blind Randomized Controlled Trial

Public title

Comparison of Local Lidocaine Infiltration, Intramuscular Morphine, and Placebo for Postoperative Pain Control After Percutaneous Nephrolithotomy (PCNL): A Double-Blind Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (aged ≥18 years) of both sexes Candidate for elective standard percutaneous nephrolithotomy (PCNL) ASA physical status class I to III Willingness to provide informed consent No chronic opioid use or dependence Non-pregnant and non-lactating women

Exclusion criteria:

History of allergy or hypersensitivity to lidocaine or morphine Coagulation disorders Untreated active urinary tract infection (positive urine culture) Severe obesity (body mass index ≥ 40 kg/m²) Need for multiple-tract PCNL or simultaneous double-J stent placement History of open kidney surgery or previous PCNL on the same kidney Abnormal renal anatomy (eg, horseshoe kidney)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To generate the random allocation sequence, SPSS version 26 was used. First, under the Transform menu, Random Number Generators was selected, and the Uniform method was set with a fixed seed of 20260321. Then, using the Compute Variable command, a uniform random variable ranging from 0 to 1 was created. After sorting cases by this random variable, blocks of size 6 were formed. Within each block of 6, 2 patients were randomly assigned to group A (local lidocaine), 2 to group B (intramuscular morphine), and 2 to group C (placebo). The final sequence consisted of a list of group codes (A, B, C) for 60 patients (20 blocks of 6). This sequence was printed on paper and placed into sequentially numbered, opaque, sealed envelopes. A nurse who was not involved in patient assessment opened the envelopes in numerical order and, based on the code inside, prepared the study drug or placebo in identical syringes. Neither the patient nor the outcome assessor was aware of the group code. No stratification was used.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind trial, the participants (patients), the outcome assessor (anesthesiology resident) , and the data analyst were blinded to group allocation. Patients were unaware of the intervention they received. Study medications (lidocaine, morphine, and normal saline) were prepared by a nurse who was not involved in patient assessment, using identical syringes labeled only with a group code (A, B, or C). The surgeon (principal investigator) could not be blinded to the nature of the intervention because of the different routes of administration (local injection in groups A and C versus intramuscular injection in group B). However, he was also unaware of the syringe content in groups A and C (both injected locally). The anesthesiology resident who assessed pain using the Visual Analogue Scale (VAS) at 6, 12, 24, and 48 hours postoperatively had no knowledge of group assignment. Likewise, the data analyst received data coded by group letter (A, B, or C) only, with no information about the actual intervention, ensuring blinding during the analysis. No Data Safety and Monitoring Committee was involved in this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of hamedan University of Medical Sciences

Street address

Department of Nephrology and Urology, Shahid Beheshti Hospital, 2nd Floor, Bolvar-e-Eram, Ghaim Square, Hamadan, Iran

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Hamadan

Postal code

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Approval date

2026-05-09, 1405/02/19

Ethics committee reference number
IR.UMSHA.REC.1405.096

Health conditions studied

1

Description of health condition studied
Calculus of kidney (Nephrolithiasis)
ICD-10 code
N20.0
ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Postoperative pain intensity
Timepoint
Measurement of pain intensity at baseline (before surgery) and then at 6 hours, 12 hours, 24 hours, and 48 hours after surgery
Method of measurement
Visual Analogue Scale, which is a 10-centimeter ruler with scores ranging from 0 (no pain) to 10 (worst imaginable pain)

Secondary outcomes

1

Description
Total dose of rescue opioid (pethidine) consumed within 48 hours after surgery
Timepoint
48 hours after the operation
Method of measurement
Recording the total amount of pethidine consumed (mg) from the patient's medical record

Intervention groups

1

Description
Control group: Infiltration of 20 mL of normal saline 0.9% (sodium chloride 0.9%), Caspian Tamin Pharmaceutical Company, administered locally (15 mL deep around the nephrostomy tract and 5 mL subcutaneously at the incision site) immediately after surgery and before skin closure, single dose, plus standard analgesic regimen (IV acetaminophen 1 g every 6 hours and IV ketorolac 30 mg every 8 hours).
Category
Treatment - Surgery

2

Description
Intervention group 1 : Infiltration of 20 mL of 2% lidocaine (containing 4 mg/kg lidocaine hydrochloride), Alborz Darou Pharmaceutical Company, administered locally (15 mL deep around the nephrostomy tract and 5 mL subcutaneously at the incision site) immediately after surgery and before skin closure, single dose, plus standard analgesic regimen (IV acetaminophen 1 g every 6 hours and IV ketorolac 30 mg every 8 hours).
Category
Treatment - Surgery

3

Description
Intervention group 2 : Intramuscular injection of 5 mg morphine sulfate (1 mL of a 10 mg/mL ampoule), Temad Pharmaceutical Company, administered during surgery after stabilization of the patient's vital signs, single dose, plus standard analgesic regimen (IV acetaminophen 1 g every 6 hours and IV ketorolac 30 mg every 8 hours).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital of Hamadan (Teaching, Research and Treatment Center)
Full name of responsible person
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Sponsors / Funding sources

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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
Hamedan 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
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Full name of responsible person
Reza Shamsollahi
Position
Urology Resident (Resident)
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual raw data will not be published due to confidentiality and lack of prior plans for public sharing.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

Full study protocol (including background, objectives, methodology, inclusion/exclusion criteria, interventions, outcomes, statistical analysis plan, and ethical considerations). The protocol is summarized in the IRCT registry and the full document will be provided upon request by the journal or researchers.

When the data will become available and for how long

From the time of acceptance of the main article by the journal (estimated about 6 months after trial registration) for a period of 5 years.

To whom data/document is available

Researchers working in academic and scientific institutions (after submitting a written request and signing a non-commercial use agreement).

Under which criteria data/document could be used

Solely for reproducing results, conducting meta-analyses, or examining methodology. Commercial use is prohibited. Requests must be justified with a clear purpose.

From where data/document is obtainable

Corresponding author (Dr. Reza Shamsollahi) via email: r.sh.1376@gmail.com

What processes are involved for a request to access data/document

Requests will be reviewed by the corresponding author within a maximum of 30 days. If approved, the protocol file (PDF) will be sent via email.

Comments