Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

English Title: Comparison of the effect of adding magnesium sulfate and midazolam to 0.5% bupivacaine spinally in reducing postoperative pain in patients who are candidates for ureteric stone surgery

Protocol summary

Study aim

Comparison of the effect of adding magnesium sulfate and midazolam to 0.5% bupivacaine spinally in reducing postoperative pain in patients who are candidates for ureteric stone surgery

Design

In this double-blind, randomized clinical trial,60 patients undergoing TUL surgery under spinal anesthesia at Amir al-Momnin Hospital, Arak, will be enrolled. Following informed written consent and verification of inclusion and exclusion criteria,

Settings and conduct

The study will be conducted in the operating room of Amir Al-Momenin Hospital in Arak. After informed consent, patients will be allocated to groups using block randomization. Patients, outcome assessors, and data analysts will be blinded to the intervention, and blinding will be maintained by an independent anesthesiologist. The patients will then be randomly allocated into two groups using a block randomization method. Spinal anesthesia will be performed at the L3–L4 or L4–L5 intervertebral space using a 25–26 gauge Quincke needle by a single operator, and patients in each group will receive the specified spinal medications. supine position, and the surgical operation will be carried out.

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Age between 18 and 60 years • American Society of Anesthesiologists physical status class I or • Candidates for transureteral lithotripsy (TUL) surgery • Body mass index less than 30 Exclusion Criteria • Patient refusal to undergo spinal anesthesia

Intervention groups

Midazolam Group (M): Patients will receive 2 mg of preservative-free midazolam in combination with 15 mg of 0.5% hyperbaric bupivacaine. Magnesium Sulfate Group (S): Patients will receive 100 mg of magnesium sulfate in combination with 15 mg of 0.5% hyperbaric bupivacaine.

Main outcome variables

average blood pressure and pulse rate ،pain ، time of arrival sensor and motor block،complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260124068652N1**
Registration date: **2026-06-17, 1405/03/27**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-17, 1405/03/27**
Update count: **0**

Registration date

2026-06-17, 1405/03/27

Registrant information

Name

Shadi Rostamikia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 905 693 4020

Email address

emadbulters1976@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-02, 1405/03/12

Expected recruitment end date

2026-07-09, 1405/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

English Title: Comparison of the effect of adding magnesium sulfate and midazolam to 0.5% bupivacaine spinally in reducing postoperative pain in patients who are candidates for ureteric stone surgery

Public title

Effect of sulfate magnesium and midazolam in reducimg pain in pation who candidates for tul

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 60 years old Asa class 1 and 2 Patients who candidates for tul

Exclusion criteria:

Existential body mass index more than 30 ssensitivness to useful drugs cardiovascular problems coagolopathy arrhythmia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated into two groups using block randomization with block sizes of 2 and 4. The random sequence will be generated by an independent individual who is not involved in participant recruitment or assessment, using the online program available on the Sealed Envelope website. After confirming eligibility criteria and obtaining informed consent, each participant will receive a unique identification number in the order of enrollment and will be assigned to one of the two groups according to the pre-generated random sequence. Allocation concealment will be ensured using opaque, sealed, and sequentially numbered envelopes containing each participant’s group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

"To ensure a double-blind design, data will be measured and recorded by an intern who is unaware of the group allocations. Medication preparation for each group will be performed by a nurse anesthetist, while the spinal anesthesia will be administered by an anesthesiologist. Consequently, due to the lack of knowledge regarding group sequences and interventions among both the patients and the outcome assessors, the study will be double-blinded."

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of arak medical university

Street address

Sardasht basij square

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2025-12-21, 1404/09/30

Ethics committee reference number

IR.ARAKMU.REC.1404.393

Health conditions studied

1

Description of health condition studied

postoperative pain in patients who are candidates for ureteric stone surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postoperative pain

Timepoint

1,2,4,612 hours after operation

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Midazolam Group (M): Patients will receive 2 mg of preservative-free midazolam (caspian pharmaceutical co , Rasht iran) in combination with 15 mg of 0.5% hyperbaric bupivacaine. the drug is administered as a single bolus injection during spinal anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group: Magnesium Sulfate Group (S): Patients will receive 100 mg of magnesium sulfate (10% solution , pasteur institue of iran) in combination with 15 mg of 0.5% hyperbaric bupivacaine. the drug is administered as a single bolus injection during spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Dr alireza kamali
Street address
Sardasht, amir almomenin hospital
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Markazi
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Phone
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr behzad khansari nezhad
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Sardasht, basij square, studious assistance
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Province
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behzad.khansarinejad@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Shadi rostamikia
Position
attend
Latest degree
Specialist
Other areas of specialty/work
Urology
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Shahid shirudi street , valiasr square , valiasr hospital
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ra.jafari009@yahoo.com
Web page address
https://irct.ir/user/trial/88874/update/public_queries_contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Shadi Rostamikia
Position

Intern

Latest degree

Ph.D.

Other areas of specialty/work

General Practitioner

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Position

Intern

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable