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Testing whether ketamine and magnesium sulfate can reduce pain after kidney removal surgery

Submission date
12/03/2026

Recruitment status
No longer recruiting

Registration date
14/03/2026

Overall study status
Completed

Last Edited
05/05/2026

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific, Principal investigator, Public

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Study information

Scientific Title
Sequence-dependent analgesic efficacy of perioperative intravenous ketamine and magnesium sulfate in patients undergoing open radical nephrectomy: a randomized, double-blind, placebo-controlled clinical trial

Study objectives
To evaluate the sequence-dependent analgesic efficacy of perioperative intravenous ketamine and magnesium sulfate in patients undergoing elective open radical nephrectomy, and to determine whether the order of administration influences postoperative pain intensity and opioid consumption.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/07/2017, Institutional Ethics Committee of the University Clinical Centre of Serbia (Pasterova 2, Belgrade, 11000, Serbia; +381 11 366 2100; eticki.odbor.ukcs@gmail.com), ref: 361/15

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Factorial

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Postoperative pain, renal cell carcinoma, radical nephrectomy, multimodal analgesia

Interventions
Patients were randomized into one of nine subgroups defined by two sequential intravenous bolus injections (Drug A administered immediately after induction of anesthesia, Drug B administered 10 minutes later): Ketamine 0.2 mg/kg, MgSO4 15 mg/kg, or placebo (0.9% NaCl) in all possible combinations. All solutions were visually indistinguishable and administered in identical syringes.
There was no postoperative continuation of the study drugs.
The total duration of active treatment was therefore approximately 10–20 minutes per participant. Postoperative follow-up was conducted for 48 hours, with pain and safety assessments at 14 standardised time points (0, 30 min, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 32, and 48 hours post-surgery).
Randomisation was performed prior to study commencement using a computer-based random number generator with block randomisation. The randomisation sequence was maintained by a designated independent coordinator. All study solutions were prepared by an anaesthesia nurse not involved in patient care, in identical syringes of equal volume, ensuring allocation concealment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ketamine; magnesium sulfate (mgso4); placebo (0.9% nacl)

Primary outcome(s)
1. Postoperative pain intensity at rest and on movement measured using Numerical Rating Scale (NRS, 0-10) at 0, 30 minutes, 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 32, and 48 hours after PACU/ICU admission

Key secondary outcome(s)

Completion date
15/02/2026

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. ASA physical status class I–III
3. Unilateral renal tumor scheduled for elective open radical nephrectomy

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
208

Key exclusion criteria
1. Resting bradycardia or AV block
2. NYHA functional class greater than 2
3. GFR less than 50 ml/min
4. Severe COPD or asthma
5. Poorly controlled arterial hypertension
6. Severe hepatic impairment
7. Elevated IOP or ICP
8. Significant psychiatric comorbidity
9. Known allergy to study medications
10. Pre-existing chronic pain syndrome
11. Regular analgesic use in the month preceding surgery

Date of first enrolment
01/08/2017

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
Serbia

Sponsor information

Organisation
University clinical center of Republika Srpska

ROR
https://ror.org/05vapw332

Funder(s)

Funder type

Funder Name
University Clinical Center of Serbia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/04/2026	05/05/2026	Yes	No
Protocol file			13/03/2026	No	No