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Comparison of dexmedetomidine and ketamine on pain after total knee arthroplasty

Submission date
13/06/2025

Recruitment status
No longer recruiting

Registration date
13/06/2025

Overall study status
Completed

Last Edited
06/01/2026

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
This study looked at two medications, dexmedetomidine and ketamine, to find out which one works better in reducing pain and the need for strong painkillers after knee replacement surgery (total knee arthroplasty). Both drugs are often used during surgery as part of a pain relief strategy called multimodal analgesia.

Who can participate?
Adults aged 18 years or over, who were scheduled for elective single-knee replacement surgery under spinal anesthesia and were physically fit

What does the study involve?
Participants were randomly placed into two groups. One group received dexmedetomidine, the other received ketamine, both during surgery. Everyone also received a femoral nerve block and standard spinal anesthesia. Pain levels, use of painkillers, vital signs, and satisfaction were monitored for 24 hours after surgery.

What are the possible benefits and risks of participating?
There may be better pain control and a lower need for opioids. No serious side effects were observed, and there were no cases of low blood pressure or slow heart rate. All patients reported high satisfaction.

Where is the study run from?
Hatay Mustafa Kemal University (Turkey)

When is the study starting and how long is it expected to run for?
June 2023 to December 2024

Who is funding the study?
Hatay Mustafa Kemal University (Turkey)

Who is the main contact?
Dr Senem Urfalı, senemurfali@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparing the effects of intraoperative dexmedetomidine and ketamine on postoperative pain in total knee arthroplasty: a randomized trial

Acronym
DK-TKA

Study objectives
It was hypothesized that intraoperative dexmedetomidine infusion would provide better postoperative pain control and reduce opioid consumption compared to ketamine in patients undergoing total knee arthroplasty.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 21/06/2023, Hatay Mustafa Kemal University Clinical Research Ethics Committee (Tayfur Sökmen Kampüsü Alahan-Antakya/HATAY, Hatay, 31060, Türkiye; +90 (0)(326) 221 33 17 - 18 - 19; rektorlukyaziisleri@mku.edu.tr), ref: 02

Study design
Single-centre double-blinded prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Total knee arthroplasty

Interventions
Patients were randomly allocated into two groups (1:1 ratio) using a computer-generated randomisation list created by an independent biostatistician before patient enrolment. Block randomisation was not used. Allocation was concealed, and both patients and outcome assessors were blinded to group assignments.

Patients were randomly assigned to receive either intraoperative dexmedetomidine infusion (1 µg/kg over 10 minutes followed by 0.5 µg/kg/h) or ketamine infusion (0.1 mg/kg/h without a loading dose) under spinal anesthesia.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexmedetomidine, ketamine

Primary outcome(s)
Total opioid consumption (in milligrams of tramadol) is measured using data obtained from the intravenous PCA device at 24 hours postoperatively.

Key secondary outcome(s))
1. Pain intensity is measured using the Visual Analogue Scale (VAS) (0 = no pain, 10 = worst pain) in both sitting and supine positions at 0, 4, 8, 12, 18, and 24 hours postoperatively
2. Need for rescue analgesia is determined based on VAS ≥4, and the administration of IV meperidine (0.3 mg/kg) is recorded during the first 24 hours
3. Hemodynamic parameters including heart rate, systolic, diastolic, and mean arterial pressure are measured using noninvasive monitoring at 0, 4, 8, 12, 18, and 24 hours postoperatively
4. Ambulation time (in hours) is recorded based on the time to first mobilization after surgery
5. Side effects including postoperative nausea and vomiting, hypotension, and bradycardia are documented based on clinical observation and medication use within the first 24 hours
6. Patient satisfaction is measured using a four-point scale (0 = poor, 1 = moderate, 2 = good, 3 = excellent) at 24 hours postoperatively

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Adult patients aged ≥18 years
2. Scheduled for elective unilateral primary total knee arthroplasty under spinal anesthesia
3. American Society of Anesthesiologists (ASA) physical status I–III
4. Provided written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
104

Key exclusion criteria
1. Body mass index (BMI) >35 kg/m²
2. Uncontrolled hypertension
3. Renal or hepatic disease
4. Mental, psychiatric or neuromuscular disorders
5. Known allergies or contraindications to dexmedetomidine, ketamine, or local anesthetics
6. Contraindications to spinal anesthesia
7. Refusal to participate in the study

Date of first enrolment
01/07/2023

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Türkiye

Study participating centre
Hatay Mustafa Kemal University, Tayfur Ata Sökmen Faculty of Medicine
Tayfur Sökmen Kampüsü (31060) Alahan-Antakya
Hatay
Türkiye
31060

Sponsor information

Organisation
Hatay Mustafa Kemal University

Funder(s)

Funder type
University/education

Funder Name
Hatay Mustafa Kemal University

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from the corresponding author (please contact Dr Senem Urfalı via senemurfali@gmail.com). The data include anonymised individual participant data (IPD) related to demographics, intervention details, opioid consumption, VAS scores, and hemodynamic parameters. Data will become available after publication of the study results and will be accessible for a period of 5 years. Access will be granted for academic purposes following approval of a written proposal. Participant consent for data sharing was obtained as part of the informed consent process. All data will be anonymised to protect patient confidentiality and comply with ethical guidelines.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	27/12/2025	06/01/2026	Yes	No