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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
13/06/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

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

Contact name
Dr Senem Urfalı

ORCID ID
https://orcid.org/0000-0003-4500-2408

Contact details
Madenli Mahallesi 3000.Sokak Borankent Sitesi C Blok Kat:2 Daire:4
Arsuz
Hatay
Türkiye
31225
+90 (0)5326331797
senemurfali@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
Nil known

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure

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

Secondary outcome measures
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

Overall study start date
21/06/2023

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
104

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

Sponsor details
Tayfur Ata Sökmen Faculty of Medicine
Serinyol Mahallesi
Alahan-Antakya/ Hatay
Türkiye
31060
+90 (326) 229 10 00, +90 (326) 221 33 17 - 18 - 19
senemurfali@mku.edu.tr

Sponsor type
University/education

Funder(s)

Funder type
University/education

Funder Name
Hatay Mustafa Kemal University

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal upon completion of the study.

Intention to publish date
01/08/2025

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