Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of dexmedetomidine versus tramadol as adjuvant in Spinal anesthesia in femur fracture surgery

Protocol summary

Study aim

1.To compare the duration of sensory and motor block produced during femur fracture surgery using dexmedetomidine and tramadol as adjuvants to spinal anesthesia. 2. To compare the adjuvant's postoperative analgesia duration and quality. 3. To compare the hemodynamic parameters between dexmedetomidine and tramadol groups.

Design

This is a two-arm, parallel-group, prospective randomized controlled clinical trial. A total of 68 eligible participants will be recruited using consecutive sampling and randomly allocated in a 1:1 ratio into two groups: dexmedetomidine (n=34) and tramadol (n=34). Randomization will be performed using a simple random allocation method.

Settings and conduct

The study will be conducted in patients undergoing femur fracture surgery under spinal anesthesia. Eligible participants will provide informed consent and will be randomly allocated to receive either dexmedetomidine or tramadol as an adjuvant. Block characteristics, postoperative pain, analgesic requirements, hemodynamic parameters, and adverse effects will be recorded.

Participants/Inclusion and exclusion criteria

Inclusions criteria Patients aged 18–65 years both male and female patient ASA I–II, undergoing femur fracture surgery under spinal anesthesia and willing to participate will be included. Exclusion criteria Patients with contraindications to spinal anesthesia, allergy to study drug Significant hepatic/renal impairment, or chronic opioid used.

Intervention groups

Participants will be randomly allocated into two groups : dexmedetomidine (n=34) and tramadol (n=34)

Main outcome variables

Primary outcomes are duration of postoperative analgesia and time to first rescue analgesic request.

Secondary outcomes include sensory and motor block duration, pain scores, analgesic consumption, hemodynamic changes, and adverse effects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260807070565N1**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date

2026-09-13, 1405/06/22

Registrant information

Name
Masaud Shah
Name of organization / entity
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-15, 1405/05/24

Expected recruitment end date

2026-12-15, 1405/09/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of dexmedetomidine versus tramadol as adjuvant in Spinal anesthesia in femur fracture surgery

Public title
Comparison of Dexmedetomidine and Tramadol as Adjuvants to Spinal Anesthesia in Femur Fracture Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients aged 18-65 yeears both male and female patients ASA physical status I or II Undergoing elective femur fracture surgery under spinal anesthesia Willing to provide written inform consent
Exclusion criteria:
contraindications to spinal anesthesia(coagulopathy,local infection,raised ICP) Known hypersensitivity to dexmedetomidine, tramadol or bupivacaine ASA physical status III or IV Significant cardiac, hepatic or renal impairment Chronic analgesic or opioid abuse
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be individually randomized in a 1:1 ratio into two groups: dexmedetomidine group and tramadol group. A computer-generated randomization sequence will be used to assign patients randomly to either group. Each patient will be assigned a study number and allocated according to the randomization sequence. No stratification or clustering will be used.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Two-arm, parallel-group randomized controlled clinical trial comparing dexmedetomidine and tramadol as adjuvants to spinal anesthesia in patients undergoing femur fracture surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of superior university Lahore
Street address
Raiwand road,kot arian,Lahore
City
Lahore
Postal code
042 111 000 078
Approval date
2024-08-24, 1403/06/03
Ethics committee reference number
ref:IRB/FAHS/REHAB/04/26/MS/RS-4101

Health conditions studied

1

Description of health condition studied
Femur fracture
ICD-10 code
S72
ICD-10 code description
Fracture of femur

Primary outcomes

1

Description
Duration of postoperative analgesia.
Timepoint
Measured from completion of spinal anesthesia until the first request for rescue analgesia (within the first 24 hours after surgery).
Method of measurement
Measured in minutes from intrathecal drug administration to the first rescue analgesic requirement. Pain will be assessed using the Visual Analogue Scale (VAS), and rescue analgesia will be given when VAS ≥4

Secondary outcomes

1

Description
Hemodynamic stability (heart rate and mean arterial pressure)
Timepoint
Baseline,5,10,15 and 30 minutes after spinal anesthesia
Method of measurement
Measured using a multi parameters monitoring and recorded as heart rate (beat/minute) and mean arterial pressure (mmHg)

Intervention groups

1

Description
Intervention group 1: Patients receiving intrathecal bupivacaine with dexmedetomidine as an adjuvant.Intervention group 2: Patients receiving intrathecal bupivacaine with tramadol as an adjuvant
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
District headquarters hospital batkhela
Full name of responsible person
Masaud shah
Street address
JX76+49W, Batkhela
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Postal code
23020
Phone
+92 314 9822371
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su91-msahw-f24-069@superior.edu.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Superior university Lahore
Full name of responsible person
Dr Usra Naeem
Street address
Raiwand road, kot arian, Lahore
City
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Postal code
54000
Phone
Email
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Web page address
https://superior.edu.pk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Superior university Lahore
Proportion provided by this source
100
Public or private sector
Private
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
Superior university Lahore
Full name of responsible person
Masaud shah
Position
Ms allied health science student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Contact

Name of organization / entity
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Full name of responsible person
Masaud shah

Position
Allied health science student

Latest degree
Bachelor

Other areas of specialty/work
Anesthesiology

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Province
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Email

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
Deidentified individual participant data will not be shared because the data are collected for academic thesis purposes and are subject to participant confidentiality and institutional ethical requirements. Data will be accessible only to the research team and authorized supervisors/institutional authorities.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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