# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 2026

# COMPARISON OF THE EFFECTIVENESS OF NALBUPHINE VERSUS TRAMADOL FOR PREVENTION OF POST SPINAL SHIVERING IN PATIENTS UNDERGOING LOWER LIMB SURGERY AT TERTIARY CARE HOSPITAL, KARACHI

## Protocol summary

**Study aim**

The main aims are: 1. To assess the incidence of post-spinal shivering in patient 2. To evaluate the efficacy . 3. To compare the safety profiles in the study population 4. To determine the optimal pharmacological approach for shivering prophylaxis in lower limb surgery patients. This study hypothesize that nalbuphine is better in effective controlling post-spinal anesthesia shivering compared to tramadol. The findings of this study will provide valuable understanding of effectiveness between nalbuphine and tramadol, and helpful for other anesthetist to optimizing perioperative care also reducing the risks of postoperative complications

**Design**

- Randomized Controlled Trial (RCT) - Parallel-group design - Single-center study - double-blinding (participants and outcome assessors blinded) - Prospective study

**Settings and conduct**

1. Study location: Department of Anesthesia, National Medical Center, Karachi. 2. Country: Pakistan. 3. Tertiary care hospital.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: 1. Patients of either sex. 2. Age 20-60 years. 3. Scheduled for lower limb surgery under spinal anesthesia. 4. American Society of Anesthesiologists (ASA) physical status ≤ 2. Exclusion Criteria: 1.Emergency surgeries, deformities of the spine, hypersensitivity to any of the drugs in the study. 2.Thyroid or neuromuscular diseases. 3.Patients on narcotics/sedatives. 4. Allergic to nalbuphine or tramadol. 5.Patients with an initial body (core) temperature >38.0°C or <36.0°C. 6.History of stroke, renal impairment, chronic obstructive pulmonary disease, asthma, chronic liver disease, and CCF

**Intervention groups**

Nalbuphine group (N) and Tramadol group (T) both receiving dose of (0.5mg/kg) intravenously over 5 minutes which is administrated after spinal anesthesia and assessed via shivering grade (0-4)

**Main outcome variables**

Incidence of post-spinal shivering (yes/no)

## General information

**Reason for update**

**Acronym**

NTPS (Nalbuphine vs Tramadol for Post-Spinal Shivering)

**IRCT registration information**

IRCT registration number: **IRCT20241106063628N1**
Registration date: **2024-11-15, 1403/08/25**
Registration timing: **prospective**

Last update: **2024-11-15, 1403/08/25**
Update count: **0**

**Registration date**

2024-11-15, 1403/08/25

**Registrant information**

**Name**
Akash Kumar
**Name of organization / entity**
National medical center
**Country**
Pakistan
**Phone**
+92 330 8431329
**Email address**
akashdosani007@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-01-01, 1403/10/12
**Expected recruitment end date**
2025-07-01, 1404/04/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
COMPARISON OF THE EFFECTIVENESS OF NALBUPHINE VERSUS TRAMADOL FOR PREVENTION OF POST SPINAL SHIVERING IN PATIENTS UNDERGOING LOWER LIMB SURGERY AT TERTIARY CARE HOSPITAL, KARACHI

**Public title**
Comparing Nalbuphine versus Tramadol to prevent Shivering after Lower limb surgery
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients of either sex, between 20-60 years of age, receiving spinal anesthesia during lower limb surgery will be included in the study. ASA ≤ 2
**Exclusion criteria:**
Patients undergoing emergency surgeries, deformities of the spine, hypersensitivity to any of the drugs in the study. Patients with thyroid or neuromuscular diseases. Patients on narcotics/sedatives. Patients allergic to nalbuphine or tramadol. Patients with an initial body (core) temperature >38.0°C or <36.0°C. Patients with h/o stroke, renal impairment, chronic obstructive pulmonary disease, asthma, chronic liver disease, and CCF will be excluded.
**Age**
From **20 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The method used is block Randomization in which using a technique of sealed opaque envelopes (SOE) to minimize selection bias, ensure comparable groups, and reduce confounding variables. Eligibility of participants are stratified by age, sex and surgery type, then randomly allocated to either Nalbuphine or Tramadol groups The randomization procedure are : 1.Assessing eligibility and obtaining informed consent 2.Stratifying participant 3.Using SOE for treatment assignment 4.Randomly allocating participants to treatment groups.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
- Sealed opaque envelopes bearing "N" (Nalbuphine) or "T" (Tramadol) are used for randomization. - Participants and outcome assessors are unaware of the treatment assignments.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
National Medical Center Ethical Research Committee (NMC-ERC)
**Street address**
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
**City**
Karachi
**Postal code**
75500
**Approval date**
2024-08-16, 1403/05/26
**Ethics committee reference number**
1571-2024

## Health conditions studied

### 1

**Description of health condition studied**
Shivering
**ICD-10 code**
R68.83
**ICD-10 code description**
Chills (without fever)

## Primary outcomes

### 1

**Description**
Shivering Assessment
**Timepoint**
initially at baseline (before intervention): immediately before administration Nalbuphine or Tramadol then, (post intervention): 15 minutes then 30 minutes, 1 hour then post surgery: 2hours
**Method of measurement**
Shivering assessment via grades 0 to 4: Grade 0: No shivering.• Grade 1: One or more of the following:

Piloerection, peripheral vasoconstriction, peripheral cyanosis with, but without visible muscle activity.• Grade 2: Visible muscle activity confined to one muscle group.• Grade 3: Visible muscle activity in more than one muscle group.• Grade 4: Gross muscle activity involving the whole body.

## Secondary outcomes

### 1

**Description**
Shivering Assessment
**Timepoint**
initially at baseline (before intervention): immediately before administration Nalbuphine or Tramadol then, (post intervention): 15 minutes then 30 minutes, 1 hour then post surgery: 2hours
**Method of measurement**
shivering assessment via grades 0 to 4: Grade 0: No shivering.• Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction, peripheral cyanosis with, but without visible muscle activity.• Grade 2: Visible muscle activity confined to one muscle group.• Grade 3: Visible muscle activity in more than one muscle group.• Grade 4: Gross muscle activity involving the whole body.

## Intervention groups

### 1

**Description**
Intervention group: Nalbuphine Group (NG)- Description: Patients receiving nalbuphine (0.5 mg/kg) intravenously over 5 minutes
**Category**
Prevention

### 2

**Description**
Intervention group: Tramadol Group (TG)- Description: Patients receiving tramadol (0.5 mg/kg) intravenously over 5 minutes
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
National Medical Center
**Full name of responsible person**
Prof.Brig.(R) Aneel Aslam
**Street address**
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
**City**
Karachi
**Postal code**
75500
**Phone**
+92 330 8431329
**Email**
Akashdosani007@gmail.com
**Web page address**
https://nmc.net.pk/

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
National Medical Center
**Full name of responsible person**
Prof.Brig.(R).Aneel Aslam
**Street address**
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
**City**
Karachi
**Postal code**
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**Email**
Akashdosani007@gmail.com
**Web page address**
https://nmc.net.pk/
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
National Medical Center
**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**
Other

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
National Medical Center
**Full name of responsible person**
Prof.Brig.(R).Aneel Aslam
**Position**
Professor
**Latest degree**
Specialist
**Other areas of specialty/work**

Anesthesiology
**Street address**
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**Province**
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
National medical center
**Full name of responsible person**
Muhammad Arslan Zahid
**Position**
Consultant
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Cardiothoracic Anesthetist
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## Person responsible for updating data

**Contact**
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National medical center
**Full name of responsible person**
Akash Kumar
**Position**
Post graduate Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Anesthesiology
**Street address**
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
**City**
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**Province**
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**Postal code**
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**Phone**
+92 330 8431329
**Email**
Akashdosani007@gmail.com
**Web page address**
https://nmc.net.pk/

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
"Nalbuphine-Tramadol Trial Dataset" Participant Data Sets: - Demographics (age, sex, weight, height) - Clinical outcomes (shivering assessment, vital signs, adverse events) - Intervention details (nalbuphine/tramadol dosage, administration time) - Follow-up data (post-operative shivering, pain scores). Specific IPD Shared: - All collected de-identified IPD for primary and secondary outcome measures - IPD collected for adverse events and serious adverse events Proforma: - Participant ID (anonymized) - Treatment group (nalbuphine/tramadol) - Shivering assessment (yes/no) - Vital signs (heart rate, blood pressure, temperature) - Adverse events (yes/no)
**When the data will become available and for how long**
6 months after completion of study
**To whom data/document is available**
It will available for Institutional Review Board (IRB). College of Physician and Surgeon Pakistan (CPSP) .
**Under which criteria data/document could be used**
Publication in peer-reviewed journals Education and training / Research purpose Presentation at Scientific conference
**From where data/document is obtainable**
National Medical Center, Karachi. Study website (After Publication) Institutional review board (IRB)
**What processes are involved for a request to access data/document**
Study Principal Investigator/ Data Sharing Committee

approves or rejects request. Requester is notify via email (approval/ Rejection)

**Comments**