Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
75500
Phone
+92 330 8431329
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
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
City
Karachi
Province
Sindh
Postal code
75500
Phone
+92 330 8431329
Email
Akashdosani007@gmail.com
Web page address
https://nmc.net.pk/

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
Street address
A-5/A, DHA Phase 1 Korangi Road, Karachi, Sindh - 75500
City
Karachi
Province
Sindh
Postal code
75500
Phone
+92 302 9205341
Email
arslan.zahid@nmc.net.pk
Web page address
https://nmc.net.pk/

Person responsible for updating data

Contact
Name of organization / entity
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
Karachi
Province
Sindh
Postal code
75500
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