

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 $>38.0^{\circ}\text{C}$ or $<36.0^{\circ}\text{C}$. 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.

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget 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

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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

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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

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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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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 be 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