Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Use of Bupivacaine with Tramadol is better than use of only Bupivacaine for post operative pain in Local Anesthesia

Protocol summary

Study aim

The aim of this study is to evaluate and compare the postoperative analgesic efficacy of bupivacaine alone versus a combination of bupivacaine and tramadol when used for local anesthesia in patients undergoing minor surgical procedures at a tertiary care hospital in Karachi. This research seeks to assess the mean postoperative pain following minor surgical procedures, as well as the need for rescue analgesia, in both groups, in order to determine whether the addition of tramadol provides superior pain control or not.

Design

Parallel group, single blinded, randomized controlled trial.

Settings and conduct

The study was conducted at the Surgical Unit 4 of Jinnah Postgraduate Medical Center and was a single blinded study where the patients were unaware of which group they have been assigned to

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: All patients undergoing elective procedure under local anesthesia Either gender. Age 18-60 years. EXCLUSION CRITERIA: Procedures Under general anesthesia. Diabetic patients, assessed by history and clinically and HbA1c >6.5% Patients with metastatic disease, assessed by history, clinically and by imaging. Patients who are I/V opioid abusers will be excluded.

Intervention groups

In Group A (bupivacaine) patients received 0.5 ml/kg of 0.25% plain bupivacaine at the surgical site, while Group B (bupivacaine with tramadol) patient received 0.5 ml/kg of 0.25% bupivacaine in combination with 1 mg/kg of tramadol.

Main outcome variables

Mean postoperative pain score using a visual analogue scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250325065151N1**
Registration date: **2025-04-23, 1404/02/03**
Registration timing: **prospective**

Last update: **2025-04-23, 1404/02/03**
Update count: **0**

Registration date

2025-04-23, 1404/02/03

Registrant information

Name
Moosa Ashfaq
Name of organization / entity
Jinnah Sindh Medical University
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-30, 1404/02/10

Expected recruitment end date

2025-05-30, 1404/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Use of Bupivacaine with Tramadol is better than use of only Bupivacaine for post operative pain in Local Anesthesia

Public title
Use of two different local anesthetic drugs Bupivacaine and Tramadol together compared with only using Bupivacaine for post operative pain management

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients undergoing elective procedure under local anesthesia Both genders Age 18-60 years

Exclusion criteria:
Procedures under general anesthesia Diabetic patients, assessed by history and clinically and HbA1c >6.5% Patients with metastatic disease, assessed by history, clinically and by imaging Patients who are I/V opioid abusers will be excluded.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method (Lottery method) will be used. Unit of randomization will be individual. Randomization strata in stratified randomization will not be applicable. The tool used will be paper slips drawn randomly from a container. Other tools like a computer software will not be used. The random sequence will be generated by drawing lots (paper slips) from a shuffled container. Allocation concealment will be carried out.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, single blinding will be implemented by ensuring that the patients (participants) are unaware of the treatment they received. The patients will be randomly assigned to either the Bupivacaine alone group or the Bupivacaine + Tramadol group using the lottery method. The anesthetic solutions will be prepared in identical syringes to prevent the patients from distinguishing between the two treatments. The patients will not be informed about which anesthetic they received, reducing the risk of reporting bias based on expectations. However, the researchers administering the anesthesia will be aware of the treatment assignments.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Jinnah Postgraduate Medical Center

Street address
Rafiqui Shaheed Road, Karachi Cantonment

City
Karachi

Postal code
75510

Approval date
2022-10-05, 1401/07/13

Ethics committee reference number
NO.F.2-81/2022-GENL/275/JPMC

Health conditions studied

1

Description of health condition studied
Postoperative Pain

ICD-10 code
R52.0

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Mean postoperative pain score

Timepoint
4,8 and 24 hours after intervention

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients received 0.5 ml/kg of 0.25% bupivacaine in combination with 1 mg/kg of tramadol

Category
Treatment - Drugs

2

Description
Control group: patients received 0.5 ml/kg of 0.25% plain bupivacaine only
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Jinnah Postgraduate Medical Center
Full name of responsible person
Prof. Syed Mehboob Alam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Jinnah Postgraduate Medical Center
Proportion provided by this source
100
Public or private sector
Public
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
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Position
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Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The study protocol outlines the methodology, objectives, and design of the research. Sharing Plan: The study protocol will be shared via email with collaborating researchers or institutions, with a link to a secure cloud storage service (e.g., Google Drive, Dropbox) where the document can be accessed and downloaded. After completion of the study, the protocol will be included as part of the publication in a peer-reviewed journal. Access Type: Open access for collaborators; the protocol will be shared as supplementary material in the publication. File Format: PDF or Word document.

When the data will become available and for how long
Availability: The raw data will become available after the study has been completed and the manuscript has been accepted for publication. The anonymized data will be shared with the public and other researchers upon publication of the study in the peer-reviewed journal which is within 6 months of publication. Duration of Availability: The data will be made available indefinitely through public repositories such as the journal's supplementary material section or a data repository (e.g., ResearchGate, PubMed, or a dedicated data repository like Dryad or Open Science Framework). Data will be accessible as long as the publication remains available or until the platform's terms and conditions change. Access Type: Anonymized data will be made publicly accessible, ensuring that patient confidentiality is maintained.

To whom data/document is available
Research Team: Full access to raw data will be available to the research team throughout the study period for analysis and reporting. Collaborators: Research collaborators, if needed for analysis or verification, will have access to the anonymized data after the study is completed and prior to publication. General Public: After publication, anonymized raw data will be made publicly available through the journal's supplementary materials, public data repositories such as ResearchGate, Open Science Framework, or the publication platform like PubMed. Other Researchers: The data will be made available to researchers interested in replicating or extending the study, with access to anonymized data for academic purposes.

Under which criteria data/document could be used
Academic and Research Purposes: The raw data can be used by other researchers for further analysis, replication studies, or meta-analyses as long as the data is anonymized to maintain patient confidentiality. Publications: Data may be used for secondary publications, such as follow-up studies or papers that compare the study's results with other research. Educational Use: The data can be used in academic settings like for teaching purposes in courses or training as long as appropriate references to the original study are made. Non-Commercial Use: Data can only be used for non-commercial purposes unless otherwise specified in the data-sharing agreement. Ethical Considerations: The data cannot be used for any purpose that might violate the privacy of the participants or compromise the integrity of the study

From where data/document is obtainable
Data can be requested from the corresponding author of the study after publication. Email Address: moosanl30@gmail.com The corresponding author will provide access to anonymized raw data through a secure platform such as cloud storage upon request for academic or research purposes.

What processes are involved for a request to access data/document
The requester sends an email to the corresponding author at the provided email address. The requester should clearly specify the data or document they wish to access, the purpose of the request and any relevant ethical or institutional considerations.

Comments