Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Analgesic Effects of Surgical Site Bupivacaine and Tramadol Infiltration After Appendectomy

Protocol summary

Study aim

Comparison of the analgesic effects of surgical site infiltration of bupivacaine versus tramadol in patients undergoing appendectomy under general anesthesia.

Design

Randomized, double-blind, parallel-group, active-controlled, phase 3 clinical trial on 80 patients (40 patients per group). Randomization will be performed using the random number generation function of SPSS software.

Settings and conduct

The study will be conducted at AL-Jumhouri Hospital ،in Neynava , Iraq. Appendectomy candidates, after confirming eligibility, will be randomly allocated to two groups. The surgeon will infiltrate the drug at the surgical site. The patient, pain assessor, and statistical analyst will be blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Age between 18 and 65 years. Candidate for appendectomy under general anesthesia. ASA physical status class I or II Ability to provide written informed consent. Exclusion Criteria : Known allergy to any of the study medications. History of chronic opioid use Severe cardiac, hepatic, renal, or advanced neurological disorders. Pregnancy or breastfeeding. Body Mass Index greater than 35 kg/m². Diagnosis of perforated appendicitis or generalized peritonitis requiring extensive surgery. Inability to communicate effectively for reliable pain score assessment.

Intervention groups

Group Bupivacaine: Receives 20 mL of bupivacaine 0.25% (50 mg) as layer-by-layer infiltration at the surgical site. Group Tramado: Receives 100 mg of tramadol dissolved in 20 mL of normal saline as layer-by-layer infiltration at the surgical site.

Main outcome variables

Postoperative pain intensity measured by VAS, at PACU arrival and at 1, 2, 4, 6, 12, and 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260428069192N3**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

Mohamad Sorani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-11, 1405/05/20

Expected recruitment end date

2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Analgesic Effects of Surgical Site Bupivacaine and Tramadol Infiltration After Appendectomy

Public title

Comparison of the Analgesic Effects of Topical Bupivacaine and Tramadol in Appendectomy Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 65 years. Candidate for appendectomy under general anesthesia. ASA physical status class I or II according to American Society of Anesthesiologists criteria. Ability to fully understand the study protocol and provide written informed consent

Exclusion criteria:

Known allergy or hypersensitivity to bupivacaine, tramadol, or any of the study medications. History of chronic opioid use or substance abuse. Severe cardiac, hepatic, renal, or advanced neurological disorders. Pregnancy or breastfeeding. Body Mass Index (BMI) greater than 35 kg/m². Diagnosis of perforated appendicitis or generalized peritonitis requiring extensive surgery. Inability to communicate effectively for reliable pain score assessment.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

n this randomized controlled clinical trial, the Simple Randomization method using computer-generated random numbers will be employed(Uniform Random Number Generator). This method is a fully probabilistic (random) approach in which each participant has an entirely equal and independent chance of being allocated to either of the two intervention groups. In this method, the randomization sequence is designed in such a way that allocation of each patient to groups is not predictable in any way and is based solely on chance and probability. The probability of allocation to each group is 50% (1:1 ratio)

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding is designed as a double-blind trial with the exception that the injecting physician is not blind, while the patient, data collector , and statistical analyst will all remain blind to the patient's group allocation. The study drugs (bupivacaine 0.25% and tramadol 100 mg dissolved in normal saline) will be prepared by an independent pharmacist in identical 20 mL syringes with clear and colorless appearance, and will be labeled only with group codes (A or B). After opening the randomization envelope, only the surgeon will be informed of the group code and will inject the corresponding drug at the surgical site. The patient, anesthesia team, nurses, and pain assessor will remain unaware of the injected drug type. The statistical analyst will receive data coded as A and B, and unblinding will be performed after analysis completion. To maintain blinding throughout the study, all team members are obligated to preserve blinding, and no information about the patient's group will be disclosed to the pain assessor or patient. In case of any accidental disclosure of the patient's group, this will be recorded as a "Breach of Blinding" in the data collection form and will be considered in the final analysis

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Public Health & Allied Medical Sciences- Tehran University

Street address

No. 17, Bastani Parizi Alley, Ghods St., Enghelab Ave., Enghelab Sq., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417744361

Approval date

2025-08-02, 1404/05/11

Ethics committee reference number

IR.TUMS.SPH.REC.1405.137

Health conditions studied

1

Description of health condition studied

Acute postoperative pain resulting from appendectomy surgical incision

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description
Postoperative pain score measured by Visual Analog Scale (VAS) at PACU arrival and at 1, 2, 4, 6, 12, and 24 hours after surgery (0–10 cm, where 0 indicates no pain and 10 indicates the worst imaginable pain).
Timepoint
PACU arrival and at 1, 2, 4, 6, 12, and 24 hours after surgery
Method of measurement
it will be measured by Visual Analog Scale (VAS)0–10 cm, where 0 indicates no pain and 10 indicates the worst imaginable pain.

2

Description
Total opioid consumption within the first 24 hours after surgery
Timepoint
within the first 24 hours after surgery
Method of measurement
Total opioid consumption after surgery in Milgram

Secondary outcomes

1

Description
Heart Rate, Systolic Blood Pressure, Diastolic Blood Pressure, and Mean Arterial Pressure
Timepoint
PACU arrival, 30 minutes after surgery, 1 hour, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours after surgery.
Method of measurement
Using standard monitoring devices (blood pressure monitor and electrocardiography) in the recovery unit and surgical ward.

2

Description
Time to First Rescue Analgesic Request
Timepoint
when the patient first requests analgesia or VAS reaches 4 or higher).
Method of measurement
Recording of exact time (minutes) from the end of surgery (extubation) to analgesic request, based on nursing documentation and recorded in the data collection form.

Intervention groups

1

Description
Intervention group: After fascial closure and before skin closure, 20 mL of bupivacaine 0.25% (equivalent to 50 mg) will be infiltrated by the surgeon in a layer-by-layer, multi-site manner at the surgical site. The injection technique is as follows: 5 mL injected into the muscle fascia, 10 mL injected into the subcutaneous tissue (in a fan-shaped manner), and the remaining 5 mL injected into the subdermal layer. Injection will be performed slowly (approximately 2 mL per 10 seconds), and the wound will not be massaged after injection.
Category
Treatment - Drugs

2

Description
Control group: After fascial closure and before skin closure, 100 mg of tramadol hydrochloride dissolved in 20 mL of normal saline will be infiltrated by the surgeon in a layer-by-layer, multi-site manner at the surgical site. The injection technique is identical to Group A: 5 mL injected into the muscle fascia, 10 mL injected into the subcutaneous tissue (in a fan-shaped manner), and the remaining 5 mL injected into the subdermal layer. Injection will be performed slowly (approximately 2 mL per 10 seconds), and the wound will not be massaged after injection.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
AL-Jumhouri Teaching Hospital in Nineveh, Iraq
Full name of responsible person
Imad Ahmed Hameed
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Phone
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emadahmad11110000@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
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1417653761

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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
Tehran University of Medical Sciences

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
Tehran University of Medical Sciences

Full name of responsible person
Mohamad Sorani

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohamad Sorani

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
All data will remain confidential in accordance with the ethical commitment, and only aggregated group-level results will be published in the form of a final article or report

Study Protocol
Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Individual participant data will not be shared. The only publishable documents include the aggregated study results in the form of the final manuscript and the Statistical Analysis Plan (SAP). Study results will be disseminated through publication in a reputable national or international peer-reviewed journal in the field of anesthesiology, as well as presentation at relevant scientific conferences

When the data will become available and for how long

Access to SAP: immediately after IRCT registration. Access to aggregated results (manuscript): submitted within 12 months of data collection completion; publicly available 6 months post-publication

To whom data/document is available

IPD will not be shared. Aggregated results (manuscript) and SAP will be publicly and unrestrictedly available to all—academic researchers, industry professionals, students, and the public—via the publishing journal and IRCT.

Under which criteria data/document could be used

IPD will not be shared. For use of aggregated results and SAP: 1. Proper citation is mandatory. 2. Direct commercial use is not permitted. 3. Compliance with research ethics is required. 4. No formal request is needed due to open-access publication.

From where data/document is obtainable

Applicants, in order of priority: 1. Publishing journal website (manuscript). 2.. Principal investigator email: mohamad.sorani@gmail.com (additional information). 3. PubMed, Scopus, and Google Scholar.

What processes are involved for a request to access data/document

No application process. Immediate, free download from journal website or Email inquiries

Comments