Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

OPIOID SPARING EFFECT OF INTRAVENOUS IBUPROFEN IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

Protocol summary

Study aim

To compare the opioid-sparing effect of intraoperative intravenous ibuprofen versus placebo in patients undergoing laparoscopic cholecystectomy, in terms of postoperative opioid consumption, pain scores, and requirement for rescue analgesia.

Design

A single-center, randomized, placebo-controlled, parallel-group trial with blinded outcome assessment involving 60 patients (30 in each group).

Settings and conduct

The study will be conducted in the Department of Anesthesia, National Hospital & Medical Center Lahore. Patients will be randomized into two groups by using the closed envelope method: the ibuprofen group (n = 30) and the control group (n = 30). The randomization will be blinded to all assessors

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 18–65 years ASA physical status I–II Patients scheduled for laparoscopic cholecystectomy Exclusion Criteria Chronic use of NSAIDs or opioids Intraoperative discontinuation of study protocol for any reason Known contraindication or hypersensitivity to study drugs (ibuprofen/tramadol)

Intervention groups

Intervention Group 1: The ibuprofen group (n = 30) will receive 400 mg (100 ml) of intravenous ibuprofen over 20 minutes, 20 minutes before extubation. Control Group: The control group (n = 30) will receive 100 ml of normal saline intravenously over 20 minutes, 20 minutes before extubation.

Main outcome variables

Total postoperative opioid consumption (tramadol dose in mg) within 24 hours after laparoscopic cholecystectomy. Postoperative pain scores using Visual Analogue Scale (VAS) at 2-hour intervals for up to 12 hours. Time to first rescue analgesia. Requirement for rescue analgesia (yes/no). Total dose of rescue analgesia administered.

General information

Reason for update

Acronym

IVI-LOC Trial

IRCT registration information

IRCT registration number: **IRCT20260701070034N1**
Registration date: **2026-07-08, 1405/04/17**
Registration timing: **prospective**

Last update: **2026-07-08, 1405/04/17**
Update count: **0**

Registration date

2026-07-08, 1405/04/17

Registrant information

Name

Muhammad Majid Khan

Name of organization / entity

National Hospital And Medical center Lahore

Country

Pakistan

Phone

+92 342 0508505

Email address

drmajid505@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-10, 1405/04/19

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
OPIOID SPARING EFFECT OF INTRAVENOUS IBUPROFEN IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY

Public title
Does Intravenous Ibuprofen Reduce the Need for Opioid Pain Medicines After Laparoscopic Cholecystectomy?

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1. Patients aged between 18 to 65 years. 2. Both Gender. 3. American Society of Anesthesiology (ASA) stage l-ll. 4. Scheduled for laparoscopic cholecystectomy.

Exclusion criteria:
l. History of long-term non-steroidal anti-inflammatory and opioid analgesic use (to eliminate potential confounding factors related to previous medication history). 2. Needing to discontinue the medication required in the study during surgery for any reason (to maintain consistency in the study protocol and avoid potential interference with the intervention).

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomized into two groups by using the closed envelope method: the ibuprofen group (n = 30) and the control group (n = 30). The randomization will be blinded to all assessors.

Blinding (investigator's opinion)
Single blinded

Blinding description
The randomization will be blinded to all assessors.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of National Hospital And Medical Center

Street address
132/3, L-Block, near sports stadium D.H.A Lahore Cantt

City
Lahore

Postal code
54810

Approval date
2024-07-26, 1403/05/05

Ethics committee reference number
NHMC/HR/1044

Health conditions studied

1

Description of health condition studied
Gallstone disease undergoing Laparoscopic cholecystectomy

ICD-10 code
K80.0

ICD-10 code description
Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description
Postoperative opioid consumption

Timepoint
24 hours post-operatively

Method of measurement
total dose of rescue analgesia administered based on VAS score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (ibuprofen group): patients will receive 400mg (100ml) of intravenous ibuprofen over 20 minutes, 20 minutes before extubation.

Category
Treatment - Drugs

2

Description
Control group: patients will receive 100 ml of intravenous normal saline over 20 minutes, 20 minutes before extubation.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Anaesthesia, National Hospital and Medical Center Lahore

Full name of responsible person
Muhammad Majid Khan

Street address
132/3, L-Block, near sports stadium D.H.A Lahore Cantt

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Lahore

Postal code
54810

Phone
+92 305 5969114

Email
drmajid505@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Hospital and Medical Center Lahore

Full name of responsible person
Muhammad Majid Khan

Street address
132/3, L-Block, near sports stadium D.H.A Lahore Cantt

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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 Hospital and Medical Center Lahore

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 Hospital And Medical center Lahore

Full name of responsible person
Muhammad Majid Khan

Position
Post graduate residenct

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
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Person responsible for scientific inquiries

Contact

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National Hospital And Medical center Lahore

Full name of responsible person
Ethics committee of National Hospital And Medical Center

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Person responsible for updating data

Contact

Name of organization / entity

National Hospital And Medical center Lahore

Full name of responsible person

Muhammad Majid Khan

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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

Individual participant data will not be shared due to confidentiality and institutional policy.

Study Protocol

No - There is not 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

No - There is not 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