

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

recruiting

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 I-II. 4.
Scheduled for laparoscopic cholecystectomy.

Exclusion criteria:

1. 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

City

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

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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 resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

National Hospital And Medical center Lahore

Full name of responsible person

Ethics committee of National Hospital And Medical Center

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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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