

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

TO STUDY THE PHARMACOKINETIC AND PHARMACODYNAMIC EFFECTS OF LIDOCAINE INFUSION ON POSTOPERATIVE ANALGESIA WITH RESPECT TO PHARMACOGENETICS

Protocol summary

Study aim

To explore lidocaine infusion can be used as anesthetic adjuvant

Design

Interventional, prospective, double-blind randomized study

Settings and conduct

This study after approval by our Institutional ethical Review Committee will be carried out in POF Hospital Wah Cantt.

Participants/Inclusion and exclusion criteria

Inclusion • ASA I and II 18-60y Exclusion • ASA, III, IV, V &, and VI • Abnormal LFT/RFT

Intervention groups

Lidocaine infusion 2ml bolus dose & the continous infusiion @ 8 drops / min till closure of incision.

Main outcome variables

L-6, IL-8 Inflammatory markers Mobilization after surgery VAS

General information

Reason for update

Acronym

LAT

IRCT registration information

IRCT registration number: **IRCT20230830059302N1**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **prospective**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Ayesha Afzal

Name of organization / entity

Riphah International University

Country

Pakistan

Phone

+92 301 5218240

Email address

afzalayesha78@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-10-02, 1403/07/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

TO STUDY THE PHARMACOKINETIC AND PHARMACODYNAMIC EFFECTS OF LIDOCAINE INFUSION ON POSTOPERATIVE ANALGESIA WITH RESPECT TO PHARMACOGENETICS

Public title

Lidocaine as anesthetic adjuvant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

- Healthy Pakistani individuals between ages 18-60 years undergoing elective abdominal cholecystectomy.
- Patients in classes I and II of the American Society of

Anesthesiologists (ASA) scale.

Exclusion criteria:

- Not of Pakistani origin
- Extremes of age
- Patients in classes III, IV, V &, and VI of the ASA scale.
- Patient with deranged Liver & renal function test (LFT/RFT)
- Pre-operative morphine consumption
- Patients on medication with immunosuppressive drugs, Non-steroidal anti-inflammatory drugs, or steroids if taking should stop them one week before surgery

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

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **300**
More than 1 sample in each individual
Number of samples in each individual: **4**
Blood samples taken at 0, 2 4 & 6 hrs after the start of surgery

Randomization (investigator's opinion)
Randomized

Randomization description
An interventional, prospective, double-blind randomized study The solutions container was assigned the code A & B. Only the anesthetist knows which solution has to be given to the patient. The researcher and the patient were kept blind

Blinding (investigator's opinion)
Double blinded

Blinding description
An interventional, prospective, double-blind randomized study (62) The solutions container was assigned the code. Only the anesthetist knows which solution has to be given to the patient. The researcher and the patient were kept blind

Placebo
Not used

Assignment
Other

Other design features
Interventional

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

BASAR

Street address

Islamic International Medical College

City

Rawalpindi

Postal code

46000

Approval date

2023-06-15, 1402/03/25

Ethics committee reference number

Riphah/IIMC/ERC/23/0262

Health conditions studied

1

Description of health condition studied

Patient undergoing Elective abdominal cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

To prove that lidocaine is a safe anesthetic adjuvant helps in early recovery and decreases the hospital load.by early mobilization

Timepoint

Samples will be taken at 0, 2, 4 & 6 hrs after the surgery

Method of measurement

BP by sphygmomanometer & plasma level of drugs by HPLC, Interleukin levels by ELISA kit, Genotyping by PCR & RFLP

2

Description

Analgesia

Timepoint

VAS

Method of measurement

Facial expression, then after 8 hours through verbal questions

Secondary outcomes

1

Description

Inflammatory markers

Timepoint

IL levels decline earlier

Method of measurement

ELISA Kit

Intervention groups

1

Description

Intervention group:

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Pakistan Ordinance Factories Hospital (POF)

Full name of responsible person

Ayesha Afzal

Street address

Pharmacology Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self Sponsored

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Self financed

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Wah Medical College

Full name of responsible person

Ayesha Afzal

Position

Associate Professor

Latest degree

Master

Other areas of specialty/work

Pharmacology/ Doctor/Professor

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Full name of responsible person

Ayesha Afzal

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Title and more details about the data/document

Patient aged between 18 to 60 years fulfilling ASA criteria of I & II undergoing elective abdominal cholecystectomy

When the data will become available and for how long

After the study completed for 10 years

To whom data/document is available

To researchers

Under which criteria data/document could be used

When someone wants the data he can contact me through email for availability

From where data/document is obtainable

From me the researcher

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

Through email

Comments