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
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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 sphygmomonometer & 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 verbel questions

Secondary outcomes

1

Description

Inflammatory markers

Timepoint

IL levels decline earlier

Method of measurement

ELISA Kit

Intervention groups

1

Description

Intervention group:

Category

Treatment - Drugs

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
Ayesha Afzal
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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
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Person responsible for updating data

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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 fufilling ASA criteria of I & II ubdergoing elective abmoniall cholecystectomy
When the data will become available and for how long
After the study completedfor 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