

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Role of Ropivacaine Infiltration in Postoperative Analgesia for Perianal Procedures: A Randomized Controlled Trial

Protocol summary

Study aim

To determine whether infiltration of ropivacaine at the surgical site reduces postoperative pain and analgesic consumption in patients undergoing perianal procedures.

Design

Two-arm parallel-group randomized placebo-controlled trial comparing perianal wound infiltration with 20 mL of 0.25% ropivacaine versus 20 mL of 0.9% normal saline at the end of surgery. Participants will be allocated in a 1:1 ratio. The study includes blinded postoperative care and blinded outcome assessment, with postoperative follow-up for 24 hours.

Settings and conduct

This trial will be conducted in Fatima Memorial Hospital Lahore, Pakistan. Patients will be recruited from the surgical OPD coming for elective Peri-Anal procedures. Study is double blinded, Participant and the data analyser/Investigator will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion: • Patients aged 20–60 years • Either gender • Patients undergoing elective perianal procedures • ASA physical status I or II Exclusion: • Known allergy to local anesthetics • Chronic opioid or analgesic use • Previous perianal surgery • Coagulopathy • Local infection at the site of infiltration

Intervention groups

Interventional Group 20 mL of 0.25% ropivacaine infiltration administered once at the end of surgery Single intraoperative administration with postoperative assessment over 24 hours Local surgical site infiltration (perianal wound infiltration) Control Group (Placebo) 20 mL of 0.9% Normal Saline infiltration administered once at the end of surgery Single intraoperative administration with postoperative assessment over 24 hours Local surgical site infiltration (perianal wound infiltration)

Main outcome variables

1) Post-operative Pain. Visual Analog Score for Pain 0-3 Mild 4-7 Moderate 8-10 Severe 2) Requirement of Post-operative analgesic requirements. 3) Time to first rescue

analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260528069554N1**

Registration date: **2026-06-03, 1405/03/13**

Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**

Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

Abdullah Ayub

Name of organization / entity

Fatima Memorial Hospital Lahore

Country

Pakistan

Phone

+92 316 7135772

Email address

rana.jee789@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-10-01, 1405/07/09

Expected recruitment end date

2027-10-01, 1406/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of Ropivacaine Infiltration in Postoperative Analgesia for Perianal Procedures: A Randomized Controlled Trial

Public title

Can Ropivacaine Help Reduce Pain After Perianal Procedures?

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

• Patients aged 20–60 years • Either gender • Patients undergoing elective perianal procedures • ASA physical status I or II

Exclusion criteria:

Known allergy to local anesthetics Chronic opioid or analgesic use Previous perianal surgery Coagulopathy Local infection at the site of infiltration

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned in a 1:1 ratio to either the intervention group or the control group using permuted block randomization with a fixed block size of eight. A computer-generated randomization sequence will be prepared by an investigator who is not involved in patient recruitment or outcome assessment. The allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes. After obtaining informed consent and confirming eligibility, the recruiting investigator will open the next envelope in numerical order to determine the participant's group assignment. This process will ensure both random allocation and allocation concealment until the time of assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

There is double blinding. Both the participants and the investigator involved will be blinded to treatment allocation. Participants randomized to the intervention group will receive ropivacaine injection, while those in the control group will receive 20 mL of normal saline placebo. The solutions will be prepared in identical syringes containing equal volumes, making them indistinguishable in appearance. An independent individual not involved in participant enrollment,

intervention administration, outcome assessment, or data analysis will prepare the solutions.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board

Street address

Shadman-1 Lahore

City

Lahore

Postal code

54000

Approval date

2026-05-04, 1405/02/14

Ethics committee reference number

FMH-16/03/2026-IRB-1881

Health conditions studied**1****Description of health condition studied**

Peri-Anal Surgical Conditions-(Fistula in ANO + Chronic Anal Fissure)

ICD-10 code

K60

ICD-10 code description

Fissure and fistula of anal and rectal regions

2**Description of health condition studied**

Peri-Anal Surgical Conditions(Haemorrhoids)

ICD-10 code

K64.2

ICD-10 code description

Third degree hemorrhoids

Primary outcomes**1****Description**

Post-operative Pain.

Timepoint

It will be assessed at 6, 12 and 24 hours post-operatively.

Method of measurement

Visual Analog Score for Pain 0-3 Mild 4-7 Moderate 8-10

Severe

Secondary outcomes

1

Description

Requirement of Post-operative analgesic requirements.

Timepoint

24hours post-operatively

Method of measurement

Milligrams of analgesics used in both the groups

2

Description

Time to first rescue analgesia

Timepoint

24 hours post-operatively

Method of measurement

Hours post-operatively when analgesia was asked

Intervention groups

1

Description

Intervention group: International Non-proprietary Name (INN):Ropivacaine Dose: 20 mL of 0.25% ropivacaine infiltration administered once at the end of surgery
Duration of Treatment: Single intraoperative administration with postoperative assessment over 24hr
Mode of Delivery: Local surgical site infiltration (perianal wound infiltration)

Category

Treatment - Drugs

2

Description

Control group: International Non-proprietary Name (INN):Normal Saline Dose: 20 mL of 0.9% Normal Saline infiltration administered once at the end of surgery
Duration of Treatment: Single intraoperative administration with postoperative assessment over 24hr
Mode of Delivery: Local surgical site infiltration (perianal wound infiltration)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Memorial Hospital Lahore

Full name of responsible person

Abdullah Ayub

Street address

Shadman-1 Lahore

City

Lahore

Postal code

54000

Phone

+92 316 7135772

Email

rana.jee789@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fatima Memorial Hospital Lahore

Full name of responsible person

Prof Khaleeq-ur-Rehman

Street address

Shadman-1 Lahore

City

Lahore

Postal code

54000

Phone

+92 42 111 555 600

Email

ali.mumtaz@fmhcmd.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fatima Memorial Hospital 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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Fatima Memorial Hospital Lahore

Full name of responsible person

Abdullah Ayub

Position

Surgical Resident/Trainee

Latest degree

Bachelor

Other areas of specialty/work

General Surgery

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Agro Flats Shadman-1 Lahore.

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Postal code
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Fatima Memorial Hospital Lahore
Full name of responsible person
Abdullah Ayub
Position
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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

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data: • Published results • Primary outcome

When the data will become available and for how long

From: After publication of main results To: No end date

To whom data/document is available

1)Anyone 2)Researchers

Under which criteria data/document could be used

1)Systematic reviews and meta-analyses 2)Health economic analyses 3)Studies testing whether findings can be repeated or confirmed 4)Teaching research methods or developing new statistical techniques

From where data/document is obtainable

Email of trial custodian, sponsor or committee:
rana.jee789@gmail.com

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

Requires approval by an ethics committee Requires a data sharing agreement between data requester and trial custodian or sponsor

Comments