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, Particpant and the data analyser/Investigator will be blinded.

Participants/Inclusion and exclusion criteria

Inlcsuion: • 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
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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
Street address
Agro Flats Shadman-1 Lahore.

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Province
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Person responsible for scientific inquiries

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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