

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of analgesic efficacy between transversus abdominis plane block and epidural following abdominal surgery

Protocol summary

Study aim

The objective of this study is to compare the post-operative analgesic efficacy of ultrasound guided transversus abdominis plane (TAP) block versus intra-thoracic epidural catheter in patients undergoing abdominal laparotomy.

Design

A non blinded, Quasi experimental interventional, single center study with two intervention groups carried out from march 2023 to September 2023.

Settings and conduct

The study was conducted in Anesthesia Department of Combined Military Hospital, Rawalpindi.

Participants/Inclusion and exclusion criteria

Inclusion criteria included all ASA-I and II male and female patients between ages 20-60 years presenting for elective or emergency abdominal laparotomy. Exclusion criteria included patients with cancer, tumors or metastatic disease, low ejection fraction, respiratory compromise, post chemotherapy, allergic to bupivacaine or lignocaine or unwilling to be included in the study, infection at site of block, coagulation disorders, patchy or failed epidural insertion and failure to perform TAP block after three unsuccessful attempts.

Intervention groups

The patients were divided into the TAP block group (Group TAP) (n=60) and the epidural group (Group Epidural) (n=60).

Main outcome variables

Primary variable observed was mean time to first rescue analgesia and objective patient satisfaction in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230829059295N1**

Registration date: **2023-09-08, 1402/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-08, 1402/06/17**

Update count: **0**

Registration date

2023-09-08, 1402/06/17

Registrant information

Name

Haroon Tariq

Name of organization / entity

Combined military hospital Rawalpindi

Country

Pakistan

Phone

+92 323 7399976

Email address

haroontariq299@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-30, 1402/01/10

Expected recruitment end date

2023-09-30, 1402/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic efficacy between transversus abdominis plane block and epidural following abdominal surgery

Public title

Comparison of transversus abdominis plane block and epidural in abdominal surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All ASA-I and II patients Patients between ages 20-60 years Patients undergoing for elective or emergency abdominal laparotomy.

Exclusion criteria:

Patients with cancer, tumors or metastatic disease, low ejection fraction, respiratory compromise, post chemotherapy and coagulation disorders, Allergic to bupivacaine or lignocaine Unwilling to be included in the study Patchy or failed epidural insertion and failure to perform TAP block after three unsuccessful attempts. Infection at site of block

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method was used for randomization of patients in to two groups i.e One group that received TAP block and the other that had epidural anesthesia. Allocation concealment was not done.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of combined military hospital

Street address

Tamizudin road , lalkurti rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2023-03-30, 1402/01/10

Ethics committee reference number

CMH/RWP/402

Health conditions studied

1

Description of health condition studied

Post operative pain relief after abdominal surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient satisfaction regarding post operative pain

Timepoint

At 24 hours

Method of measurement

Likert Scale

Secondary outcomes

1

Description

adverse effects of analgesia

Timepoint

Within 24 hours

Method of measurement

Patient's subjective complaints

2

Description

Effect on HDU stay due to pain

Timepoint

24 hrs, 36hrs, 48 hrs

Method of measurement

Duration of admission in HDU

Intervention groups

1

Description

Intervention group: Transversus Abdominis Plane (TAP) Block group. In the TAP block group (n=60), once the surgery was completed, a pain consultant performed the block under ultrasound guidance using standard technique furnished by NYSORA 11 . Bilateral TAP block was performed in all patients that underwent abdominal surgery and 15 ml of 1%lignocaine with adrenaline was injected on each side of the block..

Category

Treatment - Other

2

Description

Intervention group: Epidural analgesia group. An 18 G Smith epidural catheter Touhy needle was inserted in the epidural group (n=60) by a consultant anesthetist pre-operatively under aseptic measures with patient in the sitting position in the T6 thoracic space. Confirmation of correct placement was checked by hanging drop method and further confirmed by test dose of 5 ml 2% lignocaine with adrenaline. Once correct placement was confirmed, the catheter was secured, and surgery was started. No bolus dose of epidural was till the surgery was completed. At the end of surgery, a top-up of 10 ml of 0.125% bupivacaine was given in the epidural catheter for post-op analgesia and pain relief.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital

Full name of responsible person

Dr Haroon Tariq

Street address

Tamizzudin road, Lalkurti, Rawalpindi

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Phone

+92 51 9273426

Email

haroontariq299@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined military hospital

Full name of responsible person

Dr Rashid Iqbal

Street address

tamizudin road, lalkurti rawalpindi

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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

Combined military hospital

Proportion provided by this source

100

Public or private sector

Public

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

Combined Military Hospital

Full name of responsible person

Haroon Tariq

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

House No 318, Street 5, Sector B1, DHA Phase 1, Rawalpindi

City

Rawalpindi

Province

Punjab

Postal code

46000

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Combined Military Hospital

Full name of responsible person

Haroon Tariq

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Resident anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All collected data could be provided

When the data will become available and for how long

Data will be available for 2 years starting from October 2023 to October 2025

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Interventional studies being done on the same topic

From where data/document is obtainable

haroontariq299@gmail.com

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

Please contact on the email provided to ask for detailed data

Comments