

# 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

**City**

Rawalpindi

**Postal code**

46000

**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

**City**

Rawalpindi

**Postal code**

46000

**Phone**

+92 51 9273423

**Email**

haroontariq299@gmail.com

**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

**Phone**

+92 323 7399976

**Email**

haroontariq299@gmail.com

**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**

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haroontariq299@gmal.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Combined military hospital Rawalpindi

**Full name of responsible person**

Haroon Tariq

**Position**

Resident anesthesiology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Fax**

**Email**

haroontariq299@gmail.com

**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**