

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### INTERCOSTAL NERVE BLOCK (INB) VERSUS ERECTOR SPINAE BLOCK (ESP) FOR ANALGESIC EFFICACY IN PATIENTS WITH TRAUMATIC MULTIPLE RIB FRACTURES

#### Protocol summary

##### Study aim

The aim of this study is to compare analgesic efficacy and patient satisfaction when comparing the intercostal nerve block versus erector spinae block in patients presenting with traumatic multiple rib fractures.

##### Design

Randomized controlled trial Single center randomized interventional study

##### Settings and conduct

Conducted at Combined Military Hospital (CMH) Gujranwala Patients in Group E received intravenous 0.5% bupivacaine with 2% lignocaine diluted in distilled water to make a total volume of 20 ml given according to block guidelines under ultrasound guidance furnished by NYSORA. Patients in Group I received the similar titration of drug as 3 ml aliquots in each intercostal space under ultrasound guidance according to block guidelines furnished by NYSORA as well.

##### Participants/Inclusion and exclusion criteria

Total 380 participants randomized into two groups of 190 each Inclusion criteria included all male and female patients between ages 25-55 years presenting in the operating room for pain relief with regional block with multiple rib fractures (>2 ribs) not requiring surgical intervention admitted for observation. Exclusion criteria included patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post chemotherapy, allergy to lignocaine or bupivacaine, patients with advanced polytrauma causing hemodynamic instability, patients with oxygen saturation less than 92% after supplemental oxygen, patients with flail chest or pneumothorax and patients unwilling to be included in the study.

##### Intervention groups

Group E: To receive erector spinae block Group I: To receive intercostal nerve block

##### Main outcome variables

Primary variables measured were mean time to first rescue analgesia, total dose of intravenous analgesia needed in 24 hours and patient satisfaction for pain relief on the Likert scale 24 hours after intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230822059225N1**

Registration date: **2023-08-26, 1402/06/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-26, 1402/06/04**

Update count: **0**

##### Registration date

2023-08-26, 1402/06/04

##### Registrant information

##### Name

Taimur Afridi

##### Name of organization / entity

Combined Military Hospital Gujranwala

##### Country

Pakistan

##### Phone

+92 346 5051728

##### Email address

taimurazamafridi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-01, 1402/01/12

##### Expected recruitment end date

2023-09-01, 1402/06/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

INTERCOSTAL NERVE BLOCK (INB) VERSUS ERECTOR SPINAE BLOCK (ESP) FOR ANALGESIC EFFICACY IN PATIENTS WITH TRAUMATIC MULTIPLE RIB FRACTURES

**Public title**

ESP VERSUS INTERCOSTAL NERVE BLOCK FOR PAIN IN RIB FRACTURES

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Included all male and female patients between ages 25-55 years presenting in the operating room for pain relief with regional block with multiple rib fractures (>2 ribs) Not requiring surgical intervention for repair Under observation in the high dependency unit

**Exclusion criteria:**

Patients with metastatic disease Major cardiac or respiratory disease, low ejection fraction or post chemotherapy Allergy to lignocaine or bupivacaine Patients with advanced polytrauma causing hemodynamic instability Patients with oxygen saturation less than 92% after supplemental oxygen Patients with flail chest or pneumothorax Patients unwilling to be included in the study

**Age**

From **25 years** old to **55 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **380**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Minimum sample size came out to be 365 patients after using the WHO calculator keeping the confidence interval at 95%, margin of error at 5%. We included 380 patients in our study according to the inclusion criteria furnished. The method of randomization was non-probability consecutive after lottery method into Group E for ESP block and Group I for Intercostal nerve block intervention (190 patients in each group). Patients were randomly selected through lottery method by chits given to the resident on duty in the operating room and patients designated to each intervention were documented and recorded on an excel sheet for data record.

**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 Review Board CMH Gujranwala

**Street address**

Gujranwala Cantt

**City**

Gujranwala

**Postal code**

52250

**Approval date**

2023-03-01, 1401/12/10

**Ethics committee reference number**

CMH-GWA-00100

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

Rib fracture

**ICD-10 code**

S22.4

**ICD-10 code description**

Multiple fractures of ribs

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

Time to first dose of rescue analgesia

**Timepoint**

24 hours after intervention

**Method of measurement**

Pain score above 5 on the standard visual analog scale

**2****Description**

Total dose of analgesia given

**Timepoint**

In 24 hours after intervention

**Method of measurement**

Dose charting of intravenous nalbuphine once pain scores above 5 after intervention

**3****Description**

Patient satisfaction

**Timepoint**

24 hours after intervention

**Method of measurement**

Standard 7 point Likert scale

**Secondary outcomes**

1

**Description**

Nausea/Vomiting

**Timepoint**

In 24 hours after intervention

**Method of measurement**

Frequency of episodes by the resident anesthetist on duty in HDU

2

**Description**

Hypotension

**Timepoint**

In 24 hours after intervention

**Method of measurement**

Systolic BP <80 and Diastolic <60 mmHg monitored and charted hourly

3

**Description**

Post-procedure sedation

**Timepoint**

In 24 hours after intervention

**Method of measurement**

Digital sphygmomanometer

**Intervention groups**

1

**Description**

Intervention group: Group E: Erector spinae block group. Patients in Group E received intravenous 0.5% bupivacaine with 2% lignocaine diluted in distilled water to make a total volume of 20 ml given according to block guidelines under ultrasound guidance furnished by NYSORA

**Category**

Treatment - Drugs

2

**Description**

Intervention group: Group I: Intercostal nerve block group. Patients in Group I received the similar titration of drug as 3 ml aliquots in each intercostal space under ultrasound guidance according to block guidelines furnished by NYSORA

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Combined Military Hospital (CMH) Gujranwala

**Full name of responsible person**

Dr Taimur Azam Khan

**Street address**

Gujranwala Cantt

**City**

Gujranwala

**Postal code**

52250

**Phone**

+92 346 5051728

**Email**

taimurazamafridi@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

CMH Gujranwala

**Full name of responsible person**

Taimur Azam Afridi

**Street address**

Gujranwala Cantt

**City**

Gujranwala

**Postal code**

52250

**Phone**

+92 346 5051728

**Email**

taimurazamafridi@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

CMH Gujranwala

**Proportion provided by this source**

1

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Combined Military Hospital Gujranwala

**Full name of responsible person**

Taimur Afridi

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

CMH Gujranwala

**City**

Gujranwala

**Province**

Punjab

**Postal code**

52250

**Phone**

+92 346 5051728

**Fax**

**Email**

taimurazamafridi@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Combined Military Hospital Gujranwala

**Full name of responsible person**

Taimur Afridi

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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52250

**Phone**

+92 346 5051728

**Fax**

**Email**

taimurazamafridi@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Combined Military Hospital Gujranwala

**Full name of responsible person**

Taimur Afridi

**Position**

Consultant

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**City**

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**Province**

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**Postal code**

52250

**Phone**

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**Fax**

**Email**

taimurazamafridi@yahoo.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**

Article manuscript, data set and output SPSS sheets after approval of article by journal

**When the data will become available and for how long**

After approval of the manuscript by the journal, data will be available online indefinitely

**To whom data/document is available**

All academic institutions including residents and consultants for their academic purposes

**Under which criteria data/document could be used**

For academic purposes

**From where data/document is obtainable**

Through email after approval from the primary author Dr. Taimur Azam Afridi Email: taimurazamafridi@yahoo.com

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

Request through email to be approved by primary author  
Email already provided Usual scrutiny time from contact through email to grant of permission is approximately 7 days

**Comments**