Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Phone

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Email

taimurazamafridi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CMH Gujranwala

Full name of responsible person

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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

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
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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
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