Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Ultrasound guided erector spinae block vs. ultrasound guided intercostal nerve block for thoracic trauma pain management in the emergency department

Protocol summary

Study aim

Comparison of ultrasound guided erector spinae block with ultrasound guided intercostal nerve block for pain management of thoracic trauma in the emergency department

Design

Randomized, non-blinded, two arm parallel on 76 patients (two groups with at least 38 in each group). Simple randomization was performed using random numbers table.

Settings and conduct

This study will be performed in Bahonar Academic Hospital in Kerman, Iran. A post graduate year 3 resident of emergency medicine (EM) will perform the blocks under direct supervision of an attending physician of EM.Group 1 will be assigned to ultrasound guided erector spinae block and group 2 to ultrasound guided intercostal nerve block. The numeric pain scale score will be used for pain quantification, with 0 as the least and 10 as the worst pain possible. The pain score will be asked at 20 and 60 minutes following the procedures. If the patient does not report the least acceptable pain reduction after 20 minutes (at least 2 points lower than the initial score AND the score under 7) a dose of fentanyl (1 micrograms/Kg) will be administered intravenously. Main Outcomes are pain scores after 20 and 60 minutes and the total fentanyl dose in the emergency department. This trial could not be blinded.

Participants/Inclusion and exclusion criteria

Adult patients with thoracic trauma and initial pain score over 5 (out of 10) are included. Patients with distracting injuries, contraindications to Lidocaine, Need for surgical interventions in thorax, altered mental status, impaired pain sensation and those who refuse to participate will be excluded.

Intervention groups

Group 1: Erector spinae fascial plain block under ultrasound guidance Group 2: Intercostal nerve block under ultrasound guidance

Main outcome variables

Main outcomes are pain scores after 20 and 60 minutes and the total fentanyl dose in the emergency department.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131226015941N9**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **prospective**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date

2021-01-16, 1399/10/27

Registrant information

Name

Amirhossein Mirafzal

Name of organization / entity

Kerman University of Medical sceinces

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date
2021-06-05, 1400/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Ultrasound guided erector spinae block vs. ultrasound guided intercostal nerve block for thoracic trauma pain management in the emergency department

Public title
Erector spinae block vs. intercostal nerve block in thoracic trauma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All adult patients with thoracic trauma initial pain score over 5 using numeric pain scale (0-10)
Exclusion criteria:
Distracting injuries Altered mental status Any contraindications to Lidocaine Need for tube thoracostomy or thoracic surgery Impaired pain perception (Neuropathies, etc.) Large painful area (which can not be managed using intercostal nerve block) Patient refusal to participate
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized using simple randomization by random numbers table. Each individual will be the unit of randomization. The random sequence will be built by blindly pointing one number in the list and enter the number in the first 2 digits is between 01 and (at least) 76 (minimum sample size). This place will be assigned to the erector spinae group if the right sided digit is even and to the intercostal group if it is odd. The process will be continued until at least 38 locations are allocated for each group. Allocation concealment will not be done since this trial could not be performed blindly.
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
Ethics committee of Kerman University of Medical Sciences
Street address
Somaye crossroad, Jahad Blv., Ebne-Sina St., next to Besat Clinic
City
Kerman
Province
Kerman
Postal code
7610813159
Approval date
2021-01-02, 1399/10/13
Ethics committee reference number
IR.KMU.AH.REC.1399.137

Health conditions studied

1

Description of health condition studied
Unspecified injury of thorax (chest trauma)
ICD-10 code
S29.9XXA
ICD-10 code description
Unspecified injury of thorax

Primary outcomes

1

Description
Pain score (using numeric rating scale) 20 minutes following the procedures
Timepoint
Twenty minutes following the procedures
Method of measurement
Asking the patient

2

Description
Pain score minutes following the procedures
Timepoint
Sixty minutes following the procedures
Method of measurement
Asking the patient

3

Description
Total fentanyl dose administered

Timepoint
Six hours following admission
Method of measurement
Physician order and Nurse report

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Erector spinae fascial plain block will be performed under the real time vision by the ultrasound device (Mindray, 2012, China) The block will be performed by a senior resident of emergency medicine (EM) trained by a pain medicine fellow. The procedure will be supervised by an attending physician of EM with certification of ultrasound guided nerve blocks and 3 years of experience in the procedure. Firstly, erector spinae fascial plain will be recognized in the ultrasound view of the mid-thorax region in the affected side at the level of the transverse process of T5 (by the high frequency probe) and using a 20 gauge needle, 20 ml of 1% Lidocaine (Caspiantamin, Iran) will be injected under the fascia; tissue expansion is checked by ultrasound in the time of injection.
Category
Treatment - Other

2

Description
Control group: Intercostal nerve block will be performed under the real time vision by the ultrasound device (Mindray, 2012, China) and after proper sterile preparations. The block will be performed by a senior resident of Emergency Medicine trained by a pain medicine fellow. The procedure will be supervised by an attending physician of emergency medicine with certification of ultrasound guided nerve blocks and one year of experience in the procedure. Firstly, The rib with the most intense pain is recognized in the ultrasound view of the posterior axillary line in the affected side by the high frequency probe and using a 20 gauge needle, 5 ml of 1% lidocaine (Caspiantamin, Iran) will be injected under the inner suface of the rib; this procedure is repeated for 2 ribs upper and 2 ribs lower than the first site with 3-4 ml of 1% Lidocaine.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahonar Academic Hospital
Full name of responsible person
Amirhossein Mirafzal
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kerman University of Medical Sciences
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
Kerman University of Medical Sciences
Full name of responsible person
Amirhossein Mirafzal
Position

Assistant pofessor

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

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Position
Assistant professor

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Other areas of specialty/work
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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 data related to all patients could be shared after deidentification if requested.

When the data will become available and for how long
The data could be shared immediately after publication. No time limit is considered.

To whom data/document is available
Data will be available to all relevant academic researchers following reception of their proposal and explanation for the reason(s) of their request.

Under which criteria data/document could be used
The applicants should send their proposal to be evaluated. No specific pre-defined limit is considered.

From where data/document is obtainable
Please send an email to mirafzal@kmu.ac.ir.

What processes are involved for a request to access data/document
Data will be available in 3 weeks following sending the email with proposal attached.

Comments