

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Bamonar 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 sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1247 4638

Email address

mirafzal@kmu.ac.ir

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 (Caspianamin, 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 (Caspianamin, Iran) will be injected under the inner surface 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

Street address

Gharani St.

City

Kerman

Province

Kerman

Postal code

7618747181

Phone

+98 34 3223 5011

Email

mirafzal@kmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Somaye crossrd., Jahad blv., Kerman

City

Kerman

Province

Kerman

Postal code

7116913555

Phone

+98 34 3226 3855

Email

abpardakhty@kmu.ac.ir

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 professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Bahonar Hospital, Gharani St., Bagh-e-Melli crossrd.,
Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

mirafzal@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Bahonar Hospital, Gharani St., Bagh-e-Melli crossrd.,
Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

a.mirafzal@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amirhossein Mirafzal

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Bahonar Hospital, Gharani St., Bagh-e-Melli crossrd.,
Kerman

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 1247 4638

Fax

+98 34 1247 4638

Email

mirafzal@kmu.ac.ir

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