

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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 (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 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

**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

## 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

## 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**