# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Acheiving analgesia in chest trauma related pain in the emergency department: intravenous fentanyl or ultrasound guided erector spinae block

## Protocol summary

**Study aim**

To compare the analgesic effect of erector spinae block with intravenous fentanyl in chest trauma related pain in the emergency department

**Design**

Randomized, parallel group trial without blinding. Randomization will be done by simple randomization using random numbers table.

**Settings and conduct**

This study will be conducted in Bahonar Academic Hospital located in Kerman, Iran. Enrolled patients will undergo ultrasound guided erector spinae block (performed by a trained senior resident of emergency medicine under the supervision of an attending physician of emergency medicine with 2 years of experience) or will receive intravenous fentanyl (1 microgram/kg). Assessment of pain scores (using a numeric rating scale from 0 to 10) will be performed before and 20 minutes after analgesia by a registered nurse on duty . After 20 minutes, patients in both groups will receive 1 microgram/kg of intravenous fentanyl if pain scores does not relieve (at least 2 points); this will be repeated each 20 minutes until the required pain reduction (at least 2 points) will be achieved. pain score at 1 hour and the total consumed fentanyl will be recorded.

**Participants/Inclusion and exclusion criteria**

All patients over 16 years of age who present to the emergency deprtament with chest trauma and pain scores over 5 (of 10) will be included. Those with distracting injuries, impaired consciousness, lidocaine or fentanyl hypersensitivity, coagulopathy, sensory deficit and those who are not willing to participate or have already received pain medications will be excluded.

**Intervention groups**

Group 1 will undergo ultrasound guided erector spinae fascial plain block, while group 2 receives intravenous fentanyl (1 microgram/kg).

**Main outcome variables**

Pain score at 20 minutes after the block or fentanyl injection; pain scores at 1 hour, total fentanyl dose and adverse outcomes in each group are secondary outcomes.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20131226015941N7**
Registration date: **2019-05-12, 1398/02/22**
Registration timing: **prospective**

Last update: **2019-05-12, 1398/02/22**
Update count: **0**

**Registration date**

2019-05-12, 1398/02/22

**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**

2019-05-22, 1398/03/01

**Expected recruitment end date**

2019-08-23, 1398/06/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Acheiving analgesia in chest trauma related pain in the emergency department: intravenous fentanyl or ultrasound guided erector spinae block

**Public title**
Intravenous fentanyl vs. erector spinae block in chest trauma pain

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients over 16 years of age presenting to the emergency department with chest trauma initial pain score over 5 (from 10)

**Exclusion criteria:**
presence of distracting injuries impaired consciousness hypersensitivity to lidocaine or fentanyl presence of coagulopathy presence of any sensory impairment like peripheral neuropathy receiving pain killers before enrollment those who are not willing to participate or to continue their cooperation need for surgical intervention through the chest wall (including tube thoracostomy)

**Age**
From **16 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be randomized by simple randomization method using random numbers table. Each patient will be the unit of randomization. Even numbers will be assigned as group 1 (erector spinae block) and odd number to group 2 (intravenous fentanyl). Allocation concealment is not possible in this study.

**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 committe 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**
2019-04-23, 1398/02/03

**Ethics committee reference number**
IR.KMU.REC.1398.049

## 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

**Timepoint**
20 minutes and 1 hour after injection or block

**Method of measurement**
asking the patient by numeric rating scale

## Secondary outcomes

### 1

**Description**
total dose of intravenous fentanyl administered to achieve adequate analgesia

**Timepoint**
The first 6 hours of admission in the emergency department

**Method of measurement**
recording by the investigator

### 2

**Description**
adverse reactions of the intervention(s)

**Timepoint**
at the discharge time
**Method of measurement**
assessment by the investigator

## 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) 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, 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 - Drugs

### 2

**Description**
Control group: Intravenous fentanyl (Caspiantamin, Iran) will be administered by slow injection (during 2 minutes) under cardiac monitoring and pulse oximetry in the resuscitation room. Each dose of fentanyl will be 1 microgram/kg of estimated lean body weight (usually 65-75 microgram in an adult). The dose may be repeated if the patient does not report pain reduction by at least 2 points after 20 minutes intervals in the first hour and hourly thereafter (After the first dose the injection may be performed in both intervention or control groups).
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Bahonar Academic Hospital
**Full name of responsible person**
Amirhossein Mirafzal
**Street address**
Bagh-e-Melli
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## 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
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**Province**
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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 professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Emergency Medicine
**Street address**
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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**
All de-identified data set will be available for primary and secondary outcomes.

**When the data will become available and for how long**
Starting 1 year after publication

**To whom data/document is available**
The data will be available only for people in academic positions.

**Under which criteria data/document could be used**
No limitation considered for this part.

**From where data/document is obtainable**
please email your request to mirafzal@kmu.ac.ir The responsible person is Amirhossein Mirafzal

**What processes are involved for a request to access data/document**
The data set will be provided in one month

**Comments**