# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Sep 2026

## Comparison of Intubation fluency in patient with lung contusion via epidural analgesia with non invasive ventilation versus intravenous analgesia with facemask oxygen in patients with chest trauma.

## Protocol summary

**Study aim**
Comparison of two methods of analgesia In thoracic trauma patients to reduce mortality and morbidity in traffic accident victims In Shahid Bahonar Hospital of Kerman

**Design**
Clinical trial with control group, with parallel groups, double-blind, randomized with sample size50, of both genders

**Settings and conduct**
This clinical trial study was performed in Kerman Bahonar Hospital on 50 The patient underwent thoracic trauma from 18 to 60 years. The method of this study was to determine that the patients were divided into two groups using random allocation software.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria :Patients aged 18 to 60 yearsm,No history of previous illness,Patients with lung contusion with or without rib fracture. Exclusion criteria:Previous disease history,Pulmonary embolism,Spinal trauma,medical allergy,Need surgery and transfer to operating room,Personal dissatisfaction and unstable vital signs and long bone fractures

**Intervention groups**
The first group, after insertion of thoracic epidural catheter on admission to intensive care unit in thoracic vertebrae 6 and 7, was first given 0.5 cc of ropivacaine 0.5% and then 10 cc of ropivacaine 0.2%.Simultaneous oxygen therapy was started with Bipap with 5-10 cm of water.The second group received 5mg morphine and 30mg ketolac via peripheral vein and respiratory support was provided at the same time as Vancouver's mask.

**Main outcome variables**
The extent of pain control in patients with chest trauma epidural and systemic anesthesia combined with non-invasive ventilation and oxygen mask in prognosis and need for intubation.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190922044842N1**
Registration date: **2019-11-04, 1398/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-04, 1398/08/13**
Update count: **0**

**Registration date**
2019-11-04, 1398/08/13

**Registrant information**

**Name**
Maryam Amiri

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-08-27, 1398/06/05

**Expected recruitment end date**
2020-02-24, 1398/12/05

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of Intubation fluency in patient with lung contusion via epidural analgesia with non invasive ventilation versus intravenous analgesia with facemask oxygen in patients with chest trauma.

**Public title**
Comparison of Intubation fluency in patient with lung contusion via epidural analgesia with non invasive ventilation versus intravenous analgesia with facemask oxygen in patients with chest trauma.

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Ages 18 to 60 years No history of previous illness Patients with lung cantogen with or no gear breakage that is, for some reason, such as severe trauma,ABG changes etc need respiratory support and care in the intensive care unit

**Exclusion criteria:**
Previous disease history Pulmonary embolism Spinal trauma Drug sensitivity The need for surgery and transfer to the operating room where intubation of the patient is necessary Personal dissatisfaction Unstable vital signs Long bone fractures

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **50**

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

**Randomization description**
Patients are available by sampling method and were selected using a simple accident method with use random allocation software they were divided into two groups at a ratio of 1: 1.50 blocks including 25 people in group A and 25 people in group B.Individual randomization unit and there is no layered randomization.This study is a double blind.Analysis was performed using statistical software.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The blindness of the patient and the researcher were such that they did not know the type of anesthesia and pain control and which group they belonged to.

**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**
Ebn-e-Sina St.,Jahad Blvd.,Kerman,Iran

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کرمان

**Province**
Kerman

**Postal code**
7619813159

**Approval date**
2019-08-24, 1398/06/02

**Ethics committee reference number**
IR.KMU.REC.1398.256

## Health conditions studied

### 1

**Description of health condition studied**
Trauma-induced lung contusion patients

**ICD-10 code**
S27.32

**ICD-10 code description**
Contusion of lung

## Primary outcomes

### 1

**Description**
Assessment of pain in recipients epidural analgesia with non invasive ventilation and recipients of systemic anesthesia with oxygen mask

**Timepoint**
First in the first groupembedded thoracic epidural catheter on arrival at the intensive care unit in thoracic vertebrae 6 and 7 and ropivacaine was then administered per hour via a pump syringe.In the second group on arrival at the intensive care unit morphine and Ketrolac ampoules repeated every 6 hours, at the same time as the Venturi mask respiratory support.

**Method of measurement**
In the first group measuring response to treatment score pain,rate heart,rate respiratory,pco2 pao2 checked out.In the second group visual Pain Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group:In this group after insertion of the thoracic epidural catheter on arrival at the intensive care unit In thoracic vertebrae 6 and 7 at first 10 cc of ropivacaine 0.5% and then 10 cc of ropivacaine 0.2% per hour were administered via pump syringe.Simultaneously, oxygen therapy was started with Bipap with 5-10 cm of water, which was changed based on blood gas analysis and patient comfort.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: In this group 5mg morphine and 30mg ketolac via peripheral vein and Repeated every 6 hours respiratory support was performed at the same time as vancouver's mask, which was modified based on Fio2 blood gases.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Emergency department of Bahonar hospital in Kerman
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Kerman University of Medical Sciences
**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**
Academic

## Person responsible for general inquiries

**Contact**
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**Position**
Clinical Assistant
**Latest degree**
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available