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
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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

City
کرمان

Province
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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
Mahdi Ahmadinejad
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Sponsors / Funding sources

1

Sponsor
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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

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Maryam Amiri
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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