

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effects of intra venous and epidural fentanyl on pain relief, hemodynamic stability, airway resistance, pulmonary static compliance and arterial blood gas in patients with abdominal and thoracic trauma in ICU.

Protocol summary

Summary

60 patients with chest or abdominal trauma under mechanical ventilation who admitted to the ICU were included the study. Patients divided into two groups randomly. Each one contains 30 patients. In group 1 intravenous fentanyl at the first 24 hrs and then for the 2nd 24 hrs via epidural catheter replacement were infused. For group 2 we reversed the order. Between phase 1 and 2 for each group we put 24 hrs fentanyl washout period and for relieving pain during this phase morphine sulphate were administered each 1-2 hr when it was necessary. At 0-2-6-24-50-54 and 72 hrs blood pressure, heart rate, central vein pressure, static compliance, arterial blood gas and airway resistance were determined. SPSS16 was used for statistical analysis between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012205426N1**
Registration date: **2011-07-11, 1390/04/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-11, 1390/04/20

Registrant information

Name

Mehdi Ahmadinejad

Name of organization / entity

Anesthesiology department, Kerman University of

Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of intra venous and epidural fentanyl on pain relief, hemodynamic stability, airway resistance, pulmonary static compliance and arterial blood gas in patients with abdominal and thoracic trauma in ICU.

Public title

Comparison of the effects of intra venous and epidural fentanyl on pain relief, hemodynamic stability, airway resistance, pulmonary static compliance and arterial blood gas in patients with abdominal and thoracic trauma in ICU.

Purpose

Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: Patients with 16-80 year old age who are admitted in ICU due to chest or abdominal trauma and are under mechanical ventilation
 Exclusion criteria: Age under 16 and above 80 years old; BMI > 30; Instability of spine; renal or hepatic insufficiency, ischemic heart disease, hypertension, diabetes mellitus; massive transfusion; shock and acute respiratory distress syndrome

Age
 From **16 years** old to **80 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad street

City

Kerman

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

k/89/125

Health conditions studied

1

Description of health condition studied

chest trauma

ICD-10 code

S21.7, S22.

ICD-10 code description

Multiple open wounds of thoracic wall, Fracture of sternum, Multiple fractures of ribs, Flail chest

2

Description of health condition studied

Abdomen trauma

ICD-10 code

S31.1, S31.

ICD-10 code description

Open wound of abdominal wall, Multiple open wounds of abdomen, lower back and pelvis, Other multiple injuries of abdomen, lower back and pelvis

Primary outcomes

1

Description

heart rate-

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patients in ICU

Method of measurement

Heart rate with ECG monitoring-

2

Description

ABG

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patients in ICU

Method of measurement

ABG analyzer

3

Description

level of consciousness

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patients in ICU

Method of measurement

by GCS score

4

Description

static compliance-

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patients in ICU

Method of measurement

static compliance from patient data of ventilator

5

Description

airway resistance

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patents in icu

Method of measurement

airway resistance from patient data of ventilator

6**Description**

pain score-

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patents in icu

Method of measurement

pain score with visual analog score

7**Description**

blood pressure

Timepoint

at 0-2-6-24-50-54-72 hours after admission of patents in icu

Method of measurement

By non invasive BP monitoring of ICU

Secondary outcomes**1****Description**

Decrease level of GCS

Timepoint

GCS is evaluated every 2 houre

Method of measurement

consciousness level with GCS-

2**Description**

respiratory depression

Timepoint

respiratory rate is monitored continiously in ICU

Method of measurement

respiratory rate by icu monitoring devices

3**Description**

hypotension

Timepoint

BP is monitored every 1 hour-

Method of measurement

blood pressure with NIBP monitoring

4**Description**

Heart rate

Timepoint

heart rate is monitored continiously in ICU

Method of measurement

Heart rate with ECG monitoring-

Intervention groups**1****Description**

Insertion of epidural catheter in the level of L1-T11 for administration of fentanyl (1 mic/kg/hour) for pain relief

Category

Treatment - Surgery

2**Description**

administration of fentanyl from intravenous line (2mic/kg/hour) for pain relief

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

ICU ward, Shahid Bahonar hospital

Full name of responsible person

Dr. Mehdi Ahmadinejad

Street address

Bahonar hospital

City

Kerman

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

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Dr. Malekpour Afshar

Street address

Vice chancellor for research, Kerman University of Medical Sciences, Jahad street

City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty