Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 firs 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 reliving pain during this phase morphin 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

Country

Iran (Islamic Republic of)

Phone

+98 34 0223 5011

Email address

m.ahmadinejad@kmu.ac.ir

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 under16 and above 80 yeasr 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

Ethic 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 patents 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 patents in icu

Method of measurement

ABG analyzer

3

Description

level of consciosness

Timepoint

t 0-2-6-24-50-54-72 hours after admission of patents 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 patents 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
respratory 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 relif
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

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant professor

Other areas of specialty/work

Street address

ICU ward, Shahid Bahonar hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

+98 34 1226 0100

Email

mehdia50@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant professor

Other areas of specialty/work

Street address

ICU ward, Shahid Bahonar hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

+98 34 1226 0100

Email

m.ahmadinejad@kmu.ac.ir; mehdia50@ gmail.com

Web page address

www.kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ahmadinejad

Position

Assistant professor

Other areas of specialty/work

Street address

ICU ward, Shahid Bahonar hospital

City

Kerman

Postal code

Phone

+98 34 1223 5011

Fax

+98 34 1226 0100

Email

m.ahmadinejad@kmu.ac.ir; mehdia50@gmail.com

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