Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Analgesic effect and complications of thoracic epidural analgesia compared with IV- PCA(patient controlled analgesia) in patients under thoracic and upper abdominal surgeries

Protocol summary

Summary

Objective: comparing analgesic effects and postoperative complications between the Epidural analgesia and IV-PCA in patients under thoracic and upper abdominal surgery. Design: a randomized clinical trial is conducted. Population: inclusion criteria: 18-70 years old patients who were candidate for thoracic or upper abdominal surgery with ASA CLASS less than 3; exclusion criteria: history of prolonged use of NSAIDs and need to continue them, drug addiction, lower extremity neurologic disorders, history of coagulation disorders and ASA CLASS > 2 . The amount of pain before surgery is recorded using VAS and Verbal scale before surgery in both groups. In the epidural analgesia group, 30 minutes before general anesthesia, a catheter in the epidural space of T7-T8 or T8-T9 fixed and after surgery, 6 to 8 ml of 0.125% bupivacaine and 2 mg of morphine injected into the catheter and is repeated every 8 hours if necessary. In PCA group, after surgery, morphine (1mg/ml) to the 2.5 ml (with 10-minute intervals by the patient) will be injected through a PCA pump. The complication of analgesic methods and the amount of analgesia will be record every 24 hours to 72 hours after the operation. Intervention is performed after admission the patient in the operating room. The primary outcome is acute postoperative pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112318566N1**
Registration date: **2012-01-31, 1390/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-01-31, 1390/11/11

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamedan Univercity Of Medical Siences-vice chancellor for research

Expected recruitment start date

2012-01-05, 1390/10/15

Expected recruitment end date

2012-06-20, 1391/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic effect and complications of thoracic epidural analgesia compared with IV- PCA(patient controlled analgesia) in patients under thoracic and upper abdominal surgeries

Public title

Epidural analgesia and PCA in pain relief after surgery

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patients who were candidate for thoracic or upper abdominal surgeries; between 18 to 70 years old and ASA class<3. Exclusion criteria: history of NSAIDs usage for long times; ASA class >2; history of coagulation disorders; allergic reactions to local anesthetic drugs; patient inability for use of PCA pump; presence of significant neurologic disorders in lower limbs and addiction to opioid.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **144**
Randomization (investigator's opinion)
N/A
Randomization description
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
Hamedan Univercity of Medical Siences Ethics Committee
Street address
Mahdiye Street, Hamedan Univercity of Medical Siencies
City
Hamedan
Postal code
Approval date
2012-01-04, 1390/10/14
Ethics committee reference number
3552/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
Acute postoperative pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
Acute postoperative pain
Timepoint
Every 24 hours to 72 hours
Method of measurement
Measurement of pain as Verbal, VAS

Secondary outcomes

1

Description
Complications of analgesic method that used for patient
Timepoint
Every 24 hours to 72 hours
Method of measurement
At the time of any symptoms such as itching, nausea and vomiting, significant increase or decreas (over 20%) of blood presure ,respiratory depression and paresthesia or motor weakness of lower limbs.

Intervention groups

1

Description
Intervention in epidural group patients: after the replacement of the intravenous catheter and infusion of 500CC normal saline, 30 minutes before surgery, thoracic epidural catheter 20G through 18G needle in the intervertebral space T8-T9 or T7-T8 with Loss of resistance is placed in a sitting position. After fixing the catheter patients will undergo non-invasive monitors. A Test dose of bupivacaine% 0.25: 5ml with epinephrine 1 / 200000: 1ml is injected through the catheter. For surgical procedure all patients receive midazolam, fentanyl, thiopental and muscle relaxant for induction of anesthesia. In postoperative period a pharmaceutical composition containing 2mg of morphine and 6-8ml of 0.125% bupivacaine is injected through epidural catheter every 8 hours. Control of blood pressure and heart rate will be performed before induction of anesthesia and after transmit ion to the surgical ward, then will be recorded every 24 hours to 72 hours after the operation.
Category
Treatment - Drugs

2

Description
Intervention in PCA group: patients will be educated for proper use of PCA system in preoperative and

postoperative periods. After surgery, morphine (1mg/ml) to the 2.5 ml (within 10-minute intervals by the patient) will be injected through a PCA pump. After surgery, patients with certain commands for analgesia are transmitted to the ward. In all patients every 24 hours to 72 hours after surgery, amount of analgesia and the rate of complications, including complications due to surgery will be recorded. While patients are being discharged, they are questioned to determine the level of satisfaction.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

BESAT Hospital

Full name of responsible person

Dr Vahideh Shahnazari

Street address

BESAT Hospital, General Operation Room, Motahhari Avenue, Resalat Square, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan Univercity of Medical Sciences- vice chancellor for research

Full name of responsible person

Dr Haydar Tavilani

Street address

Hamedan Univercity of Medical Sciences, Mahdie Avenue

City

Hamedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan Univercity of Medical Sciences- vice chancellor for research

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

Hamedan Univercity of Medical Sciences

Full name of responsible person

Dr Vahideh Shahnazari

Position

MD, Anesthesiology Resident

Other areas of specialty/work

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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