Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Effect of Adding Ultrasound-Guided Paravertebral Block to Continuous Intravenous Analgesia in Patients Undergoing Laparotomy

Protocol summary

Summary

1) Objectives: Evaluation of effect of adding ultrasound-guided paravertebral block to continuous intravenous analgesia in patients undergoing laparotomy 2) Design: in this randomized clinical trial we will assign 21 patients for each group randomly. 3) Setting and Conduct: Paravertebral block will be applied postoperatively in the intervention group, intravenous analgesia will be administrated in patients of the both groups. During 48 hours of the study, one of our colleagues who is blinded to groups will gather and analyze the data. 4) Participants: Inclusion criteria: Patients with American Society of Anesthesiologists (ASA) I–III scheduled for upper abdominal laparotomy that ranged in age from 18–80 years. Exclusion criteria: contraindication to regional anesthesia (preoperative hemostasis disorder or a local or general infection), history of allergic reaction to local anesthetic , a past medical history of asthma, chronic renal failure or hepatic dysfunction, history of opium abuse; history of neurological, neuromuscular or psychological disorders and pregnancy 5) Interventions: Intervention Group: ultrasound-guided paravertebral block with ropivacaine hydrochloride 0.2% (Naropin 10mg/ml, 10ml polyamp, ASTRAZENECA) 20 cc for each side in T7-T8 level plus continuous intravenous analgesia filled with fentanyl (Fentanyl, Abureyhan, Iran) 20cc with 80cc normal saline with infusion rate of 4ml/hour. Control Group: continuous intravenous analgesia filled with fentanyl 20 cc with 80 cc normal saline with infusion rate of 4 ml per hour. If patients experience “visual analogue scale” (VAS) above three, Pethidine HCL (0.5 mg per kg) will be administered intravenously during 48 after surgery. 6) Main Outcome Variable: “visual analogue scale”, total dosage of opioid

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303227984N8**
Registration date: **2013-05-04, 1392/02/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-04, 1392/02/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences, Tehran,Iran

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of Adding Ultrasound-Guided

Paravertebral Block to Continuous Intravenous Analgesia in Patients Undergoing Laparotomy

Public title
Effect of Paravertebral Block in Decreasing of Post Operative Pain of Laparotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: American Society of Anesthesiologists (ASA) I–III patients scheduled for upper abdominal laparotomy who ranged in age from 18–80 years. Patients were excluded if they exhibited a contraindication to regional anesthesia (preoperative homeostasis disorder or a local or general infection), history of allergic reaction to local anesthetic , a past medical history of asthma, chronic renal failure or hepatic dysfunction, history of opium abuse; history of neurological, neuromuscular or psychological disorders and pregnancy
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Room 501, 5th Floor, Central Office of Tehran University of Medical Sciences, Keshavarz Bolvard
City
Tehran
Postal code
Approval date
2012-11-08, 1391/08/18
Ethics committee reference number
91.130.1927.د

Health conditions studied

1

Description of health condition studied
Patientis Undergoing Laparatomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post Operative Pain
Timepoint
2,6,12,24,48 Hour After Operation
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Total Dosage of Opioid
Timepoint
During 48 Hours after Surgery
Method of measurement
mg/ Nursing Report

Intervention groups

1

Description
Intervention Group: ultrasound-guided paravertebral block with ropivacaine hydrochloride 0.2% (Naropin 10mg/ml, 10ml polyamp, ASTRAZENECA) 20 cc for each side in T7-T8 level plus continuous intravenous analgesia filled with fentanyl (Fentanyl, Abureyhan, Iran) 20cc with 80cc normal saline with infusion rate of 4ml/hour.
Category
Treatment - Drugs

2

Description
Control Group: continuous intravenous analgesia (CIA) filled with fentanyl (Fentanyl, Abureyhan, Iran) 20cc with 80cc normal saline with infusion rate of 4ml/hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Vice Chancellor for Research of Tehran University of Medical Sciences
Full name of responsible person
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Tehran University of Medical Sciences , Ghods St, Keshavarz Blv,
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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 of Tehran 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

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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