

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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 administered 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

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 5758

Email address

farnadimani@yahoo.com

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

Ethics committee reference number
91.130.1927.5

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

Health conditions studied

1

Description of health condition studied

Patients Undergoing Laparotomy

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

Farnad Imani

Street address

Niyayesh St, Sattarkhan St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotoohi

Street address

Tehran University of Medical Sciences , Ghods St, Keshavarz Blv,

City

Tehran

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

Contact

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Farnad Imani

Position

Associate Professor of Anesthesiology and Pain Medicine

Other areas of specialty/work**Street address**

Department of Anesthesiology and Pain, Rasoul-Akram Medical enter, Niayesh St, Sattar-khan Av

City

Tehran

Postal code**Phone**

+98 216650905

Fax**Email**

farimani@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Associate professor of Anesthesiology

Other areas of specialty/work**Street address**

Deatpment of Anesthesiology and Pain Medicine/ Rasoul Akram Medical Center

City

Tehran

Postal code**Phone**

+98 21 6650 9059

Fax**Email**

farimani@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeid Safari

Position

Resident of Anesthesiology

Other areas of specialty/work**Street address**

Department of Anesthesiology and Pain, Rasoul-Akram Medical Center, Niayesh St, Sattar-khan Av

City

Tehran

Postal code**Phone**

00

Fax**Email**

drsafari.s@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