# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Sep 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**
**Name of organization / entity**
Vice Chancellor for Research of Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Akbar Fotoohi
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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

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## Person responsible for updating data

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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*