

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of spinae plane block and retrolaminar block, under ultrasound guidance, on pain after laparoscopic upper abdominal surgery

Protocol summary

Study aim

Comparison of the effect of spinae plane block and retrolaminar block, under ultrasound guidance, on pain after laparoscopic upper abdominal surgery

Design

Clinical trial with control group, with parallel groups, double blinded, randomized, phase 3

Settings and conduct

In this clinical trial study, 70 patients who were candidates for upper abdominal laparoscopic elective surgery referred to Rasoul-e-Akram and Firoozgar hospitals were randomly divided into two groups. In this case, the patient and the statistical analyzer are blind and the main outcome is pain.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients' consent to enter the study, Patients with ASA <1 & 2, Patients aged 20-60 years, Patients undergoing upper abdominal laparoscopic surgery. Exclusion criteria: Emergency patient, History of ropivacaine allergy, Patients who have received analgesia in a recent day, Patients with a Body mass index >35, Patients with or underlying liver and kidney disease and coagulopathy, Patients addicted to opioids

Intervention groups

Intervention group 1: spinae plane erector block under ultrasound guidance Intervention Group 2: Retrolaminar block under ultrasound guidance

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N28**

Registration date: **2021-04-04, 1400/01/15**

Registration timing: **prospective**

Last update: **2021-04-04, 1400/01/15**

Update count: **0**

Registration date

2021-04-04, 1400/01/15

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-22, 1400/02/02

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of spinae plane block and retrolaminar block, under ultrasound guidance, on pain after laparoscopic upper abdominal surgery

Public title

The effect of spinae plane block and retrolaminar block on pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' consent to enter the study Patients with ASA <1 & 2 Patients aged 20-60 years Patients undergoing upper abdominal laparoscopic surgery

Exclusion criteria:

Emergency patients History of ropivacaine allergy Patients who have received analgesia in a recent day Patients with a Body Mass Index>35 Patients with or underlying liver and kidney disease and coagulopathy Patients addicted to opioids

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients, using random allocation software, were randomly divided into spinae plane block and retrolaminar block groups. By entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers. If we enter the number "70" in this software, it generates 35 "Control " names and 35 "Intervention" names, which are randomly distributed and presented as a list. Patients are grouped according to this list.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the statistical analyzer were unaware that the patient was exposed to the spinae plane block and retrolaminar block methods. Blocking was performed by an anesthesiologist in the operating room for randomly selected patients before the operation under general anesthesia. The groups are provided to the statistical analyzer in the form of codes A and B for analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town

City

Tehran

Province

Tehran

Postal code

1433933111

Approval date

2020-11-14, 1399/08/24

Ethics committee reference number

IR.IUMS.FMD.REC.1399.495

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

After the end of surgery and 20 minutes, 2 hours, 4 hours, 6 hours, 12 hours and 24 hours after surgery

Method of measurement

Using Numeric Rating Scale (NRS)

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

After the end of surgery and twenty minutes, 2 hours, 4 hours, 6 hours, 12 hours and 24 hours after surgery

Method of measurement

poor:0,moderate:1,good:2,very good:3,excellent:4

Intervention groups

1

Description

Intervention group: In the group that intends to perform the Spinae plain erector block, the patients are placed in the lateral position after monitoring, and on the surgical side after prep and drape, the curve ultrasound probe is located longitudinally at the T7 vertebrae (process transducer) (Lower scapula border) and after specifying the border of the transducer of the upper and lower lobe processes, the needle enters the skin and subcutaneous tissue in Plane and is directed to the erector muscle of the spinae plain. A volume of 20 cc of 0.1% ropivacaine (made by Cobel company) is injected into the muscle fascia of the erector spinae plain (behind the process transducer).

Category

Treatment - Drugs

2

Description

Control group: In the group that intends to perform the retrolaminar block, the patients are placed in the lateral position after monitoring, and on the surgical side after prep and drape, the curve ultrasound probe is located longitudinally at the T7 vertebrae (process transducer) (Lower scapula border) and after determining the lamina of the vertebra and its prickly appendage, we insert the needle 1 to 1.5 cm laterally into the prickly appendage and move towards the caudal or cranial to reach the vertebral lamina. A volume of 20 cc of 0.1% ropivacaine (made by Cobel company) is injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Poupak Rahim Zadeh

Street address

Department of pain, 4th Floor, Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh "St.", Sattarkahn "Ave.", Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abas Motavalian

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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Other areas of specialty/work

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available