Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Ultrasound-guided erector spinae plane block effect on the degree of the post laparoscopic cholecystectomy pain

Protocol summary

Study aim

Determination of the ultrasound-guided erector spinae plane block effect on the degree of the post laparoscopic cholecystectomy pain

Design

Clinical trial, with tow parallel groups, single blind, accidental with number of samples 62 and 31 sample in each group.

Settings and conduct

After selection of the patient, getting satisfaction, and monitoring in the recovery unit, the patient is positioned left laterally, the right side is prep and drep, the probe of sonography is located longitudinally at the level of T7 (lower border of scapula) and after determination the lower and upper transverse processes, the needle is inserted in plane toward the erector spinae plane muscle. 20 cc Ropivacaine 0/2% is injected into the fascia of erector spinae plane muscle (behind the transverse process). A PCIA pomp containing 12 cc fentanyl in 100 cc (6microgram /1 cc) is connected to patient in both groups. The flow of the pomp will be zero and the use of the bolus bottom is instructed to the patient. (bolus = 2 cc) the patient is delivered 12-mcg of fentanyl each time the pump is pressed (in one hour at most 48-mcg fentanyl). In the control group only the aforementioned pomp with the same setting and contents is inserted.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ASA =< 2 patients with the age of 20-65 years old Exclusion criteria: Emergent patients, History of allergy to Ropivacain, analgesic consumption during the last 24 hours, BMI > 35 liver disease, renal disease and coagulopathy, Changing the plan of the surgery to the open cholecystectomy, occurrence of any problem during the operation

Intervention groups

Investigation of the ultrasound-guided erector spinae plane block effect on the degree of the post laparoscopic cholecystectomy pain

Main outcome variables

Degree of the pain in rest mood and coughing after the surgery during the specific time intervals

General information

Reason for update

In the design section, a randomized study was mentioned, but in the randomization section, "non-randomized" was mentioned, which was corrected. Also a secondary outcome was the administration of meperidine, which was corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N25**
Registration date: **2020-01-24, 1398/11/04**
Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**
Update count: **1**

Registration date

2020-01-24, 1398/11/04

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6650 9059

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-01, 1398/11/12

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Ultrasound-guided erector spinae plane block effect on the degree of the post laparoscopic cholecystectomy pain

Public title

Effect of the ultrasound-guided erector spinae plane block on the degree of post laparoscopic cholecystectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with ASA =< 2 patients with the age of 20-65 years old under laparoscopic cholecystectomy

Exclusion criteria:

Emergent patients History of allergy to Ropivacain Patients received analgesic during the last 24 hours Patients with BMI > 35 Patients with liver disease, renal disease and coagulopathy or a history of it Changing the plan of the surgery from the laparoscopy to the open cholecystectomy or occurrence of any problem during the operation

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects; it means we will have 15 blocks and also one block of 2 patients (Totally 62 patients). Then, within each block, subjects will be randomly assigned to intervention or control group . Random assignment will be done using a random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a single-blind technique in which the person recording the information has no idea regarding the control or case group is used.

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

Vice-chancellor for research and technology of Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.IUMS.FMD.REC.1397.287

Health conditions studied

1

Description of health condition studied

Laparoscopic cholecystectomy

ICD-10 code

K80.0

ICD-10 code description

Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description

The degree of the pain based on the Numerical Rating Scale criterion

Timepoint

0 means at the time of arrival to the recovery, 20 minutes after the implementation of the block, 2, 4, 6, 12, and 24 hours after the surgery

Method of measurement

The degree of the pain based on the Numerical Rating Scale criterion

Secondary outcomes

1

Description
The amount of the opioid used during the first 24 hours after the surgery in milligrams

Timepoint
0 means at the time of arrival to the recovery, 20 minutes after the implementation of the block, 2, 4, 6, 12, and 24 hours after the surgery.

Method of measurement
Based on the amount of the used opioid reported by the person recording the information in the questionnaire in milligrams

Intervention groups

1

Description
Intervention group:After the operation, upon arrival the patient to the recovery unit and monitoring, the patient is positioned left laterally, the right side is prep and drep, the probe of sonography is located longitudinally at the level of T7 (lower border of scapula) and after determination the lower and upper transverse processes, the needle is inserted in plane toward the erector spinae plane muscle. 20 cc Ropivacaine 0/2% is injected into the fascia of erector spinae plane muscle (behind the transverse process). A PCIA pomp containing 12 cc fentanyl in 100 cc (6microgram pro 1 cc) is connected to patient in both groups. The flow of the pomp will be zero and the use of the bolus bottom is instructed to the patient. (bolus = 2 cc) the patient is delivered 12-mcg of fentanyl each time the pump is pressed (in one hour at most 48-mcg fentanyl).

Category
Treatment - Other

2

Description
Control group: After the operation, upon arrival the patient to the recovery unit and monitoring, a PCIA pomp containing 12 cc fentanyl in 100 cc (6microgram pro 1 cc) is connected to patient. The flow of the pomp will be zero and the use of the bolus bottom is instructed to the patient. (bolus = 2 cc) the patient is delivered 12-mcg of fentanyl each time the pump is pressed (in one hour at most 48-mcg fentanyl).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram Hospital

Full name of responsible person
Dr. Poupak Rahimzadeh

Street address
Rasoul Akram Hospital, Mansouri St., Niyayesh Ave., Satarkhan St.

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1445613131

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p-rahimzadeh@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Seyed Abas Motevalian

Street address
Iran University Of Medical Sciences, next to Milad Tower, Hemat Highway

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1449614535

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motevalian.a@iums.ac.ir

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
Dr. Poupak Rahimzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable