

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

comparative study of the effect of analgesia of preemptive and postoperative Transversalis Abdominis plane block under ultrasound guidance in patients undergoing elective laparoscopic Cholecystectomy.

Protocol summary

Study aim

comparative study of the effect of analgesia of preemptive and postoperative Transversalis Abdominis plane block under ultrasound guidance in patients undergoing elective laparoscopic Cholecystectomy.

Design

This study is a single blind clinical trial in which the number of patients is determined according to the sample size formula and a simple randomization method is used, and using a table of random numbers, patients are assigned to two treatment groups. The sample size in this study is 76 patients, which are divided into two groups of 38.

Settings and conduct

This study is performed in Rasoul Akram Hospital in Tehran and after obtaining patient satisfaction and approval of the ethics committee, patients are randomly divided into two groups. In the first group, After anesthetizing the patient, the Transverse Abdominis block is performed with Ropivacaine before performing laparoscopic cholecystectomy, and in the second group, sensory block is performed after the Surgery. This study is single blind and the person analyzing the information is unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 20-60 years under Laparoscopic Cholecystectomy, Patients with ASA 1 & 2 anesthesia score
Exclusion criteria: History of Ropivacaine allergy, Patients with BMI > 40, Emergency patients

Intervention groups

After patient satisfaction and the approval of the ethics committee, patients are randomly divided into two groups. In the first group, the patient is first anesthetized, and then the Transverse Abdominis block is performed with Ropivacaine before performing Laparoscopic cholecystectomy, and in the second group,

Regional block is performed after the Surgery.

Main outcome variables

Pain, Nausea, Vomiting

General information

Reason for update

The sample size written (58 patients: 29 in each group) is not correct and in fact 76 patients and 38 patients in each group is correct.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N26**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **prospective**

Last update: **2021-09-09, 1400/06/18**

Update count: **2**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9059

Email address

p-rahimzadeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2021-01-18, 1399/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative study of the effect of analgesia of preemptive and postoperative Transversalis Abdominis plane block under ultrasound guidance in patients undergoing elective laparoscopic Cholecystectomy.

Public title

Comparison of regional anesthesia on pain control in Cholecystectomy surgery with two methods before and after surgery.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 20-60 years under Laparoscopic Cholecystectomy Patients with ASA 1 & 2 Anesthesia score

Exclusion criteria:

History of Ropivacaine allergy. Patients with BMI> 40. Emergency patients

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a simple randomization method is used, which is done using a table of random numbers. To use the number of random numbers, we first determine the reading path of the table numbers (for example, top, bottom, left or right). Then we assume certain numbers for each group (for example, even numbers for intervention A and odd numbers for intervention B). Then we touch on one of the numbers and move in one of the predetermined directions and record the numbers and assign them to different groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, a person who is responsible for analyzing statistical data is not aware of the treatment process and study groups and the information is provided to that person in groups A and B.

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

2020-02-03, 1398/11/14

Ethics committee reference number

IR.IUMS.FMD.REC.1398.484

Health conditions studied**1****Description of health condition studied**

Cholecystectomy

ICD-10 code

K91.86

ICD-10 code description

Retained cholelithiasis following cholecystectomy

Primary outcomes**1****Description**

Pain

Timepoint

After surgery

Method of measurement

Pain questionnaire

Secondary outcomes**1****Description**

Nausea

Timepoint

After surgery

Method of measurement

Self-report by the patient and recorded in the questionnaire

hrfaiz@hotmail.com

Sponsors / Funding sources

2

Description

Vomiting

Timepoint

After surgery

Method of measurement

Self-report by the patient and recorded in the questionnaire

Intervention groups

1

Description

Intervention group: In the first group, after induction of general anesthesia and in sterile conditions in the supine position (SUPINE) with linear probe of ultrasound (SonoSite made in USA) and with sterile syringe with 20 cc of Ropivacaine 0.25% in each part (Ropivacaine maylan made in france) and with Spinal needles No. 23 (dr japan) are blocked.

Category

Treatment - Devices

2

Description

Intervention group: In the second group, after the end of the surgery and before the patient's extubation and in sterile conditions in the supine position (SUPINE) with linear probe of ultrasound (SonoSite made in USA) and with sterile syringe with 20 cc of Ropivacaine 0.25% in each part (Ropivacaine maylan made in france) and with Spinal needles No. 23 (dr japan) are blocked.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Poupak Rahimzadeh

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 6650 9059

Email

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abas Motavalian

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 6650 9059

Email

poupak_rah@hotmail.com

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

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran
Postal code
1433933111
Phone
+98 21 6650 9059
Email
hrfaiz@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kaveh Latifi
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 6650 9059
Email
dr.latifikaveh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Kaveh Latifi
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 6650 9059
Email
h_bf69@yahoo.com

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