Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

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

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 Cholecystestomy.

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 Rupivacaine 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

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Poupak Rahimzadeh

Name of organization / entity
Iran University of Medical Sciences

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Iran (Islamic Republic of)

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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 Cholecystestomy.

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 Rupivacaine 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

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
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Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Poupak Rahimzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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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