Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison between intraperitoneal versus transversus abdominis plane block by ropivacaine for postoperative analgesia in laparoscopic cholecystectomy

Protocol summary

Study aim
Comparison between intraperitoneal versus transversus abdominis plane block by ropivacaine for postoperative analgesia in laparoscopic cholecystectomy

Design
Double-Blinded Randomized Clinical Trial

Settings and conduct
68 patients will be compared in two groups of 34 patients in Bualisina transplant hospital and in these two groups, the effect of Transversus abdominis plane block by ropivacaine and intraperitoneal administration of ropivacaine to control postoperative pain in laparoscopic cholecystectomy are compared.

Participants/Inclusion and exclusion criteria
Major inclussion criteria: Patients aged 18 to 65 years with ASA class I & II who are candidates for laparoscopic cholecystectomy exclusion criteria: Allergy to any local anesthetic; Conductive heart diseases that prevent the use of local anesthetics; Patients taking painkillers for other chronic pain; Patients with a history of drug use or alcoholism; BMI> 35; Previous abdominal surgery; Patients who are unable to express pain score for any psychological reason.

Intervention groups
In the first intervention group (group I), 30 ml of 0.2%(Made by Multeni Company) ropivacaine enters the peritoneal space through the trocar. In intervention group 2: (T group) after the end of surgery and before the patient woke up, under the ultrasound guidance transversus abdominis block (TAP block) by an anesthesiologist with 30 ml of ropivacaine 0.2%(Made by Multeni Company) (15 ml per Side) is done.

Main outcome variables
Postoperative pain, The patient's pain is measured, and recorded by the recovery staff based on the VAS criteria or scoring of pain sensation and by the ward staff after discharge from the recovery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190511043550N4**
Registration date: **2022-03-06, 1400/12/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-06, 1400/12/15**
Update count: **0**

Registration date
2022-03-06, 1400/12/15

Registrant information

Name
Ashkan Panah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3647 4270

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panah@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-14, 1400/11/25

Expected recruitment end date
2022-07-16, 1401/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between intraperitoneal versus transversus abdominis plane block by ropivacaine for postoperative analgesia in laparoscopic cholecystectomy

Public title
Comparison between intraperitoneal versus transversus abdominis plane block by ropivacaine for postoperative analgesia in laparoscopic cholecystectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Obtaining informed consent Patient aged 18 to 65 years with ASA class I & II who is a candidate for laparoscopic cholecystectomy

Exclusion criteria:
Conductive heart diseases that prevent the use of local anesthetics. Patients taking painkillers for other chronic pain Patients with a history of drug use or alcoholism BMI> 35 Patients who are unable to express pain score for any psychological reason Previous abdominal surgery Allergy to any local anesthetic

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the block randomization method. Samples (68 patients) by random block method with blocks of 4 and 8 including 34 participants in two treatment groups, intervention group 1 with 34 participants and in intervention group 2 Also, with 34 participants, will be identified using a table of random numbers extracted from the relevant software. Matching will be done then based on the obtained blocks and the sequence of drug allocation in the operating room will be injected to the people. This study is a double-blind study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs are prepared by an anesthesiologist who does not know how to perform the study and is delivered to the anesthesiologist in the operating room. Recovery will not give them any information and thus the patient, recovery nurse and inpatient ward, and data analyzer will be referred to the blind study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2021-12-20, 1400/09/29

Ethics committee reference number
IR.SUMS.MED.REC.1400.562

Health conditions studied

1

Description of health condition studied
laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
post operative pain

Timepoint
The patient's pain is measured at 0, 2, 4, 8, 12, 18 and 24.

Method of measurement
The patient's pain is measured, and recorded by the recovery staff based on the VAS criteria or scoring of pain sensation and by the ward staff after discharge from the recovery.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: (Group I) 30 ml of 0.2% ropivacaine (made by Multeni company) enters the peritoneal space through the trocar

Category

Treatment - Drugs

2

Description

Intervention group:2: (Group T) after the end of surgery and before the patient woke up, under the guidance of ultrasound transversus abdominis block (TAP block) by anesthesia with 30 ml of ropivacaine 0.2% (made by Multeni company) (15 ml in Each side) is done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu Ali Sina Hospital

Full name of responsible person

pooya vatankhah

Street address

Fars Province, Sadra, Sadra Hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab memarpoor

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

paria dinparvar

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Latest degree

Subspecialist

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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available