

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 inclusion 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

Email address

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 memarpour

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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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Ashkan panah

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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