

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of local infiltration and intra-peritoneal instillation of Ropivacaine effect on post-op pain, nausea, vomiting and analgesic requirement in laparoscopic cholecystectomy

Protocol summary

Study aim

comparison of local infiltration and intra-peritoneal instillation of Ropivacaine effect on post-op pain, nausea, vomiting and analgesic requirement in laparoscopic cholecystectomy

Design

double blinded randomized clinical trial, phase 3 with parallel group design, has control group, on 120 patients, by rand excel analysis

Settings and conduct

In this double blinded study, 120 patients which candidate for elective or semi-elective laparoscopic cholecystectomy on Madani hospital enrolled and divided to 3 groups randomly. At the end of surgery and during anaesthesia, first group received 20 cc 0.5% Ropivacaine intra-dermally in port's place, second group as same but intra-peritoneally after cholecystectomy in hepatic bed. And control group received nothing. In recovery room and in 2-4-6-12-24 post-op hours, pulse rate, blood pressure, pain (by visual analogue scale), nausea, vomiting and analgesic requirement were evaluated. The participants and evaluator have no information about group allocation.

Participants/Inclusion and exclusion criteria

inclusion criteria: people aged 18-70 yr-cardiologist permission for surgery-no history of headache or migraine- normal renal and hepatic function exclusion criteria: history of previous surgery in abdomen-concurrent pathology in biliary ducts-conversion to open surgery-severe hemodynamic changes during operation-addiction-cardiac disease

Intervention groups

In this double blinded study, 120 patients which candidate for elective or semi-elective laparoscopic cholecystectomy on Madani hospital enrolled and divided to 3 groups randomly. First group received 20 cc 0.5% Ropivacaine intra-dermally in port's place, second

group at same dosage but intra-peritoneally after cholecystectomy in hepatic bed. And control group received nothing.

Main outcome variables

pain-nausea-vomiting-analgesic requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230523058263N1**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

SOHEYLA FARAJI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 360 8876

Email address

sohayla_f7_2012@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-19, 1402/11/30

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of local infiltration and intra-peritoneal instillation of Ropivacaine effect on post-op pain, nausea, vomiting and analgesic requirement in laparoscopic cholecystectomy

Public title

Comparison of local infiltration and intra-peritoneal instillation of Ropivacaine effect on post-op pain, nausea, vomiting and analgesic requirement in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

people aged between 18-70 permission for surgery from cardiologist consultant no history of headache or migrane normal renal and hepatic function

Exclusion criteria:

history of previous surgery in abdomen concurrent pathology in billiary ducts conversion to open surgery severe hemodynamic changes during operation addiction people whom have cardiac diseases consist of heart failure, ischemic heart disease arrythmia

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization is used in this study. Lenght of block is 6 for each treatment groups, it means that each block consists of 2 persons from intervention and 2 persons from control group. We have intervention group 1(A), group 2(B) and control group(C). Thus according to $n! / (r!(n-r)!)$ there will be 20 of 6pcs subgroup like (AA, BB, CC) and its different states. Then by using Excel, randomly, one of these blocks will be choosen and based on A B C in block, eligible persons allocated to treatment or control groups and continued to appropriate study volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blinded study, so that evaluator and participants don't know about group allocation. We

inform participants about the procedure and that they receive one of treatments randomly and it is not possible for patients to detect which group they are in.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Alborz medical university comitee

Street address

Alborz medical science.Taleqani blvd,karaj

City

karaj

Province

Alborz

Postal code

3149779453

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.ABZUMS.REC.1402.042

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

cholecystectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain-nausea-vomiting-analgesic requirement

Timepoint

recovery room-2-4-6-12-24 post-op hours

Method of measurement

by questionnaire and visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: First group receive 20 cc 0.5% Ropivacaine intra-dermal in port's place. Second group as same but intra-peritoneally and third group (control) which received nothing.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Madani hospital

Full name of responsible person

Faraji soheyla

Street address

Jahanshahr, madani Square, madani hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mohamadi Hamed

Street address

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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

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Faraji Soheyla

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Person responsible for updating data

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Karaj University of Medical Sciences

Full name of responsible person

Faraji soheyra

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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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 further 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

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

not indicated

When the data will become available and for how long

not indicated

To whom data/document is available

not indicated

Under which criteria data/document could be used

not indicated

From where data/document is obtainable

not indicated

What processes are involved for a request to access data/document

not indicated

Comments