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 Rupivacaine 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 laparascopic cholecystectomy on Madani hospital enrolled and divided to 3 groups randomly. At the end of syrgery 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 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-cardiac disease

Intervention groups
In this double blinded study, 120 patients which candidate for elective or semi-elective laparascopic 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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Karaj

Province

Alborz

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3149779453

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+98 26 3442 7001

Email

info@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohamadi Hamed

Street address

medical science university-Taleqani blvd-Karaj

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Tehran

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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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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Latest degree
Medical doctor

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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