Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of analgesic effect of the of the combination of transversus abdominis plane (TAP) and rectus sheath blocks between ultrasound- guided versus laparoscopic-guided in laparoscopic cholecystectomy

Protocol summary

Study aim
A comparative study of analgesic effect of the of the combination of transversus abdominis plane (TAP) and rectus sheath blocks between ultrasound- guided versus laparoscopic-guided in laparoscopic cholecystectomy

Design
A double-blind randomized clinical trial with parallel groups and phase 3 will be conducted on 100 patients. In one group the combination of TAP and rectus sheath blocks will be done under ultrasound guidance and in the other group the combination of the same blocks will be done under laparoscopic guidance. Randomization will be performed with the block randomization method using Random allocation software.

Settings and conduct
In this study, patients undergoing laparoscopic cholecystectomy in Imam Hossein hospital of Shahid Beheshti university of medical sciences will be enrolled. The study will be conducted as a double-blind clinical trial that the patient and outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria
In this study, 100 patients undergoing laparoscopic cholecystectomy with age between 18 to 80 years will be included. The main exclusion including drug abusers, a body mass index (BMI) higher than 30 kg/m2, having previous abdominal surgeries, and pregnancy.

Intervention groups
For patients after induction of general anesthesia, in one group the combination of TAP and rectus sheath blocks with 20 cc ropivacaine 0.2% for each block (totally 40 cc) will be done under ultrasound guidance and in the other group the combination of the same blocks will be done under laparoscopic guidance . In the laparoscopic method, after observing the internal space through a 10 mm trocar and creating two holes with a No. 18 needle on each side of the abdominal wall, the blocks will be done using anatomical landmarks.

Main outcome variables
Duration of analgesia, dosage of analgesic drug; pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170515033986N5**
Registration date: **2023-08-07, 1402/05/16**
Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**
Update count: **0**

Registration date
2023-08-07, 1402/05/16

Registrant information

Name
Nazli Karami
Name of organization / entity
Urmia University of Medical Siences
Country
Iran (Islamic Republic of)
Phone
+98 44 3346 9932
Email address
karami.n@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-09-22, 1402/06/31

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of analgesic effect of the of the combination of transversus abdominis plane (TAP) and rectus sheath blocks between ultrasound- guided versus laparoscopic-guided in laparoscopic cholecystectomy

Public title

A comparative study of analgesic effect of the of the combination of transversus abdominis plane (TAP) and rectus sheath blocks between ultrasound- guided versus laparoscopic-guided

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing laparoscopic cholecystectomy Age between 18 and 80 years Patients with physical status one and two according to the criteria of the American Anesthesia Association (ASA I, II)

Exclusion criteria:

Drug abusers Body mass index above 30 kg/m2 Having previous abdominal surgeries History of psychological and neurological diseases Pregnancy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups using the block randomization method based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total determined sample size will be entered, and then in the block section, the Block randomization method will be implemented. According to the total sample size (100 patients), 25 blocks of 4 will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted as a double-blind clinical trial. The patient and the main investigator, who will assess the outcomes, will blind to patient's allocation in one of the intervention groups. Blocks will be performed by an anesthesiologist and surgeon (other than the outcome assessor). So, the list of computer-generated numbers will be given to the anesthesiologist. The physician will assign patients to groups based on computer-generated numbers. Finally, the name of groups will be label with the letters 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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences., Erabi Ave., Daneshjou Blvd., Tehran., Iran.

City

Tehran

Province

Tehran

Postal code

19839693113

Approval date

2023-07-02, 1402/04/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.204

Health conditions studied

1

Description of health condition studied

Analgesia after laparoscopic cholecystectomy surgery

ICD-10 code

MG31.2

ICD-10 code description

Acute postoperative pain, not elsewhere classified

Primary outcomes

1

Description

Duration of analgesia

Timepoint

From the administration of the block to the administration of the first analgesic drug up to 24 hours after the surgery

Method of measurement

Minute

2

Description
Dose of analgesic drug (Morphin)
Timepoint
Up to 24 hours after the surgery
Method of measurement
Milligram

3

Description
Pain severity
Timepoint
2, 6, 12 and 24 hours after the surgery
Method of measurement
NRS scale (Numerical Rating Scale)

Secondary outcomes

1

Description
Heart rate
Timepoint
Before and 2, 6, 12 and 24 hours after the surgery
Method of measurement
Monitoring

2

Description
Systolic blood pressure
Timepoint
Before and 2, 6, 12 and 24 hours after the surgery
Method of measurement
Monitoring

3

Description
Diastolic blood pressure
Timepoint
Before and 2, 6, 12 and 24 hours after the surgery
Method of measurement
Monitoring

Intervention groups

1

Description
Intervention group:In group one after induction of general anesthesia, the combination of TAP and rectus sheath blocks with 20 cc ropivacaine 0.2% for each block (totally 40 cc) will be done under ultrasound guidance by an anesthesiologist.
Category
Treatment - Surgery

2

Description
Intervention group: In group two after induction of general anesthesia, the combination of TAP and rectus sheath blocks with 20 cc ropivacaine 0.2% for each block (totally 40 cc) will be done under laparoscopic guidance by a surgeon.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Nazli Karami
Street address
Imam Hossein Hospital., Shahid Madani Ave., Tehran., Iran.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
Email
karami.n@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences., Shahid Chamran Blvd., Yemen Ave., Erabi Ave., Tehran., Iran.
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9331
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Nazli Karami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57154-89397

Phone

+98 44 3345 7286

Email

karami.n@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Nazli Karami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

57154-89397

Phone

+98 44 3245 7286

Email

karami.n@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Nazli Karami

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

City

Tehran

Province

West Azarbaijan

Postal code

57154-89397

Phone

+98 44 3345 7286

Email

karami.n@umsu.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

The results will be published as an article and the data will not be published

From where data/document is obtainable

Corresponding author email: karami.n@umsu.ac.ir

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

Corresponding author email: karami.n@umsu.ac.ir

Comments