Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Pain Degree of Patients Receiving Analgesia with Abdominal Nerve Block in Patients Undergoing Laparoscopic Cholecystectomy: A Clinical Trial Study

Protocol summary

Study aim
Comparison of the Pain Degree of Patients Receiving Analgesia with Abdominal Nerve Block in Patients Undergoing Laparoscopic Cholecystectomy

Design
The clinical trial is a controlled, parallel-group, double-blind, randomized, phase 3 trial on 50 patients, using block randomization.

Settings and conduct
Our study population is patients undergoing laparoscopic cholecystectomy surgery at the Imam Reza Hospital (AS) Educational and Medical Center in Birjand in 1403. The patients will be randomly divided into two groups as follows: A) The patient received the narcotic pethidine at a dose of 25 mg intravenously. B) Transverse abdominal nerve block (TAP) using 20 ml of 0.25% Ropivacaine Any complications such as nausea, vomiting, dizziness, respiratory depression, ataxia, dry mouth, tremor, diplopia, itching, paresthesia, allergic reaction, and hemodynamic disturbances and arrhythmias are recorded. In case of a score of 4 to 6, ketorolac is administered at a dose of 30 mg intravenously at most every six hours, and for a pain score of 7 to 10, 50 mg pethidine or 5 mg morphine is administered subcutaneously.

Participants/Inclusion and exclusion criteria
Patients between 18 and 65 years of age, who are in ASA class I and II and underwent laparoscopic cholecystectomy. Informed consent is required to participate in the study. Exclusion criteria also include sensitivity to the drugs used, use of narcotics, use of anticoagulants, previous history of upper gastrointestinal bleeding, severe renal or hepatic disease, or psychiatric disorders.

Intervention groups
A) The patient received the narcotic pethidine at a dose of 25 mg intravenously. B) Transverse abdominal nerve block (TAP) using 20 ml of 0.25% Ropivacaine

Main outcome variables
Pain Severity, Cumulative Analgesic Dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250420065407N1**
Registration date: **2025-07-04, 1404/04/13**
Registration timing: **prospective**

Last update: **2025-07-04, 1404/04/13**
Update count: **0**

Registration date
2025-07-04, 1404/04/13

Registrant information

Name
mohamad talvari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 164 6985

Email address
mohammadtlv1997@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Pain Degree of Patients Receiving Analgesia with Abdominal Nerve Block in Patients Undergoing Laparoscopic Cholecystectomy: A Clinical Trial Study

Public title
Evaluation of the effect of abdominal nerve block in laparoscopic cholecystectomy patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age 18 - 65 being classified as ASA I or II having informed consent
Exclusion criteria:
allergy to the drugs used in the study use of narcotic drugs use of anticoagulant medications history of upper GIB having severe real and hepatic diseases and psychiatric disorders
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, first we create blocks of four including BABA, BAAB, ABBA, ABAB and write them on a piece of paper and put them in a sealed envelope. Then one of these envelopes is selected and the patient is placed by the anesthesiologist (who is not involved in the data collection and analysis) and the next three patients are determined on this basis and the desired intervention is performed in the recovery room by the anesthesiologist. For the other patients, their placement in different groups is done on the same basis.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double-blind study, so that the subject and the evaluator are unaware of the allocation status. In this way, the subject is unaware of the contents of the syringes, which are identical in shape and quantity. The evaluator also measures clinical and diagnostic measurements using coding that is unknown to him/her.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Moalem Ave, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
000000000
Approval date
2024-10-28, 1403/08/07
Ethics committee reference number
IR.BUMS.REC.1403.276

Health conditions studied

1

Description of health condition studied
سنگ کیسه صفرا
ICD-10 code
K80.0
ICD-10 code description
Calculus of gallbladder with acute cholecystitis

Primary outcomes

1

Description
Pain score based on visual analog scale (VAS) in subjects who underwent Transversus abdominis plane block after cholecystectomy after surgery
Timepoint
Pain score based on visual analog scale (VAS) in subjects who underwent Transversus abdominis plane block after cholecystectomy at 1, 6, 12, and 24 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: People who received 25 mg of pethidine intravenously after cholecystectomy

Category

Treatment - Surgery

2

Description

Intervention group: People who underwent abdominal transverse nerve block using 20 ml of 0.25% Ropivacaine after cholecystectomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital (AS) Educational and Medical Center in Birjand

Full name of responsible person

Azam Bagheri

Street address

Taleghani Ave, Imam Reza Hospital (AS) Educational and Medical Center

City

Birjand

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South Khorasan

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9714811151

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erh@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Masoud Yousefi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Azam Bagheri

Position

assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
Access period starts from 2026

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
To continue studies on the subject under study

From where data/document is obtainable
Via the email and contact numbers below public_r@bums.ac.ir 0098 56 32395000

What processes are involved for a request to access data/document
Contact the Research Committee of Birjand University of Medical Sciences and access will be granted after approval by the University Ethics and Security Committee.

Comments