

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Post-operative Analgesic efficacy of ultrasound-guided sub costal transversus abdominis plane(TAP) block for laparoscopic Cholecystectomy

Protocol summary

Study aim

Determination of TAP block effects on postoperative pain control, opioids consumption rate, nausea and vomiting incidence

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

This study will be performed on 60 ASA class I-II patients, the ages of 20--65 years. After obtaining of an informed consent, they will be allocated to two groups by block random sampling.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-65 years patients scheduled elective laparoscopic cholecystectomy. Exclusion criteria: patient refusal, allergy to local anesthetics, coagulopathy, BMI > 35, previous abdominal surgery, pregnancy, addiction

Intervention groups

TAP GROUP: At the end of the surgery, under ultrasound guidance, 0.2% bupivacaine 20 ml will be injected between rectus abdominis and transverse abdominis at subcostal region. This block will be done bilaterally.
CONTROL GROUP: The transverse abdominal plane block will not be done. In both groups, the pain severity by visual analogue scale (VAS), nausea and vomiting incidence, need to meperidine and metoclopramide will be evaluated. Time frame of assessments: during recovery room stay, at 4h, 8h, 12h and 24h. All patients will be evaluated before surgery and also will be told them about the VAS, where 0=no pain and 10=worst imaginable pain. In both groups, all patients and the evaluating person will not be aware of being or not being intervention. For nausea: 0=none, 1=mild, 2=moderate, 3=severe

Main outcome variables

severity of pain, opioid consumption, nausea and

vomiting incidence during recovery and up to 24 hours after surgery

General information

Reason for update

Acronym

TAP

IRCT registration information

IRCT registration number: **IRCT20180325039148N1**

Registration date: **2018-05-17, 1397/02/27**

Registration timing: **prospective**

Last update: **2018-05-17, 1397/02/27**

Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Saeed Jalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 0001

Email address

jalilis45@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-20, 1397/03/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Post-operative Analgesic efficacy of ultrasound-guided sub costal transversus abdominis plane(TAP) block for laparoscopic Cholecystectomy

Public title

Effect of abdominal wall block on post cholecystectomy pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients within 20-60 years undregoin laparoscopic Cholecystectomy Body Mass Index below 30

Exclusion criteria:

pregnancy Allergy to local anesthetics sepsis Addiction

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks will be performed for this trial.Each block has 4 samples,two TAP block and two control with different orders.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients(control and intervention groups) after giving necessary explanations will be enrolling in abdominal block group or control group .The anesthetist who is responsible for evaluating of outcomes ,will be blinded about doing or not doing of abdominal plane block.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Gavazanng Blvd.,Mousavi Hosp.

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.ZUMS.REC.1396.322

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

Sub costal Transversus Abdominal Plane Block

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

pain rating in Visual Analogue Scale

Timepoint

During recovery,At 4h,8h,12h,24h after surgery

Method of measurement

Visual Analogue Scale questionnaire

2**Description**

Post operative need to opioid analgesic

Timepoint

During recovery,At 4h,8h,12h,24h after surgery

Method of measurement

Opioid amounts(mg)

3**Description**

post operative Nausea and vomiting

Timepoint

During recovery,At 4h,8h,12h,24h after surgery

Method of measurement

Categorical Scoring System for nausea

Secondary outcomes**1****Description**

Need to postop analgesic
Timepoint
During recovery, At 4h, 8h, 12h, 24h after surgery
Method of measurement
Analgesic amounts (mg)

Intervention groups

1

Description

Intervention group: This randomized study will be enrolled patients with American Society of Anesthesiologists (ASA) physical status I-II aged 18-65 years, undergoing laparoscopic cholecystectomy at Zanzan mousavi Research and Training Hospital. The operation will be done under General Anesthesia. TAP GROUP: At the end of the surgery, under ultrasound guidance, 0.2% bupivacaine 20 ml will be injected between rectus abdominis and transverse abdominis at subcostal region. This block will be done bilaterally. IN intervention and control groups, the pain severity by visual analogue scale (VAS), nausea and vomiting incidence, need to meperidine and metoclopramide will be evaluated. Time frame of assessments: during recovery room stay, at 4h, 8h, 12h and 24h. All patients will be evaluated before surgery and also will be told them about the VAS, where 0=no pain and 10=worst imaginable pain. In both groups, all patients and the evaluating person will not be aware of being or not being intervention. For nausea
: 0=none, 1=mild, 2=moderate, 3=sever

Category

Treatment - Other

2

Description

Control group: There won't be any special intervention or TAP block.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mousavi Hospital
Full name of responsible person
Saeed Jalili
Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanzan University of Medical Sciences
Full name of responsible person
Shoghli Alireza
Street address
Gavazang Blvd., Mousavi hospital
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Web page 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

Zanzan 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
Zanzan University of Medical Sciences
Full name of responsible person
Saeed Jalili
Position
Associate professor
Latest degree
Specialist

Other areas of specialty/work

Anesthesiology

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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 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

No - There is not 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