

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/m<sup>2</sup>, 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 Sciences

##### **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**

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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.

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**Province**

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**Postal code**

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**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**

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**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**

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**Other areas of specialty/work**

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**Postal code**

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**Phone**

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**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**