

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of intravenous injection of Caffeine on reducing pain after laparoscopic Cholecystectomy

#### Protocol summary

##### Study aim

Determining the effect of injectable Caffeine on reducing pain after surgery in laparoscopic Cholecystectomy

##### Design

A clinical trial with a control group, with parallel groups, three-blind, on 60 patients, Randomized by the method of Balanced Block Randomization

##### Settings and conduct

This study is conducted on candidates for laparoscopic Cholecystectomy referring to educational-therapeutic centers of Qazvin University of Medical Sciences. After training and informed consent, they are randomly assigned to the experimental group or the control group. Demographic information is entered into the checklist. The experimental group is injected with Caffeine and the control group is injected with Normal Saline. The pain level of the patient is recorded 10, 30, and 60 minutes after the intervention. If the patient has pain, Pethidine is injected. The amount of pain and the amount of Pethidine in both groups will be compared. The medicine is in closed-coded envelopes. The anesthesiologist, patient, analyzer, and project manager are blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for Cholecystectomy in the age range of 15-60; non-inclusion criteria: pregnancy and breastfeeding and abortion; smoking, alcohol, and drugs; chronic mental and physical illness; Disabilities; taking Corticosteroid, antihistamine, and painkillers; Allergy to Caffeine and Pethidine; history of surgery.

##### Intervention groups

After entering recovery, the experimental group is injected with Caffeine at a dose of 1 mg/kg, and the control group is injected 3cc of Normal Saline. The pain level of the patient is recorded 10, 30, and 60 minutes after the intervention. For pain intensity between 4 and 6, 0.25 mg/kg of Pethidine, and between 7 and 10, 0.5 mg/kg of Pethidine is injected.

##### Main outcome variables

Pain score; Dosage of Pethidine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221205056716N1**

Registration date: **2023-03-11, 1401/12/20**

Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**

Update count: **0**

##### Registration date

2023-03-11, 1401/12/20

##### Registrant information

##### Name

Mohammadreza Shabnam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6001

##### Email address

tikokhan@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-05, 1402/02/15

##### Expected recruitment end date

2023-08-23, 1402/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intravenous injection of Caffeine on reducing pain after laparoscopic Cholecystectomy

#### Public title

Effect of Caffeine injection on pain after Cholecystectomy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age range 15-60 years Candidate for Cholecystectomy surgery Informed consent

##### Exclusion criteria:

Pregnancy and breastfeeding and abortion less than 3 months Hyperthyroidism History of smoking, alcohol and drugs Chronic mental and physical illness (Schizophrenia, Diabetes, etc.) Vision and hearing problems and other disabilities Corticosteroids, Antihistamines, and painkillers consumption for a long time (at least 2 months) Allergy to Caffeine and Pethidine History of surgery

#### Age

From **15 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The method of random allocation in this study is Balanced Block Randomization. 6 blocks AABB- ABAB\_ ABBA- BBAA- BABA\_ BAAB are numbered based on 1 to 6 and numbers 1 to 6 are selected from the table of random numbers and placed together. Then they are replaced with numbered blocks

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The anesthesiologist receives the drugs which are coded in closed envelopes and injects them into the patients. Coding is done by one of the colleagues of the project and the doctor, anesthesiologist, analyzer, and patient are blinded.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

##### Street address

Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin

##### City

Qazvin

##### Province

Qazvin

##### Postal code

3415613911

##### Approval date

2023-03-01, 1401/12/10

##### Ethics committee reference number

IR.QUMS.REC.1401.337

## Health conditions studied

### 1

#### Description of health condition studied

Patients undergoing laparoscopic cholecystectomy

#### ICD-10 code

K80

#### ICD-10 code description

Cholelithiasis

## Primary outcomes

### 1

#### Description

Pain level after laparoscopic cholecystectomy

#### Timepoint

10, 30 and 60 minutes after the operation

#### Method of measurement

Ruler-like grading system (Visual Analog Scale) from 0 (no pain) to 10 (the most severe pain imaginable)

### 2

#### Description

The amount of Pethidine consumed

#### Timepoint

Until exiting recovery

#### Method of measurement

Record the amount of injected doses in the checklist

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: After entering the operating room, the patients undergo laparoscopic cholecystectomy under general anesthesia. After entering recovery, the experimental group was given caffeine injection drug by the anesthesiologist as an analgesic with a dose of 1 mg on a medicinal plant with medicinal characteristics: caffeine citrate 10 mg (3 ml) from Kimia drug company - maximum 60 mg per dose. It is injected intravenously to reduce pain. The pain level of the patient is recorded 10, 30, and 60 minutes after the intervention by a trained doctor or nurse. After the necessary coordination with the surgeon and the recovery nurses, for pain intensity between 4 and 6, 0.25 mg/kg of Pethidine, and for intensity Pain between 7 and 10, 0.5 mg/kg of Pethidine is injected and recorded in the patient's file.

### Category

Treatment - Drugs

## 2

### Description

Control group: After entering the operating room, the patients undergo laparoscopic cholecystectomy under general anesthesia. After entering recovery, 3cc of normal saline is injected intravenously into the control group. The pain level of the patient is recorded 10, 30, and 60 minutes after the intervention by a trained doctor or nurse. After the necessary coordination with the surgeon and the recovery nurses, for pain intensity between 4 and 6, 0.25 mg/kg of pethidine, and for intensity Pain between 7 and 10, 0.5 mg/kg of pethidine is injected and recorded in the patient's file

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Velayat hospital

#### Full name of responsible person

Mohammadreza Shabnam

#### Street address

22 Bahman Blvd, Tavon Square, Elahiye Quay,  
Minodar Town

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34719 76161

#### Phone

+98 28 3379 0620

#### Email

Clinical\_research@qums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Qazvin University of Medical Sciences

#### Full name of responsible person

Seyed Mahidi Mirhashemi

#### Street address

Mavaddat Alley ,Research and Technology deputy,  
Shahid Beheshti Blvd, Qazvin

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34199-15315

#### Phone

+98 28 3333 6001

#### Email

researchdpt@qums.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

#### Full name of responsible person

Mohammadreza Shabnam

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

#### Street address

Bahonar street

#### City

Qazvin

#### Province

Qazvin

#### Postal code

34199-15315

**Phone**  
+98 28 3333 6001  
**Email**  
tikokhan@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Shabnam  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
22 Bahman Blvd, Tavon Square, Elahiye Quay,  
Minodar Town  
**City**  
Qazvin  
**Province**  
Qazvin  
**Postal code**  
34199-15315  
**Phone**  
+98 28 3333 6001  
**Email**  
tikokhan@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Shabnam  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**

22 Bahman Blvd, Tavon Square, Elahiye Quay,  
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**Email**  
tikokhan@yahoo.com

## 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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be shared after individuals are de-identified

### When the data will become available and for how long

Access starts 6 months after results are published

### To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

Any kind of analysis on the delivered data is allowed

### From where data/document is obtainable

Refer to Dr. Shabnam's email "tikokhan@yahoo.com"

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

After publishing the article, the applicant can send a clear request to the author to access the data by sending an email. So, after reviewing the request within 2 weeks, access to data and information is allowed.

### Comments