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

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Mahidi Mirhashemi

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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
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

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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
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