Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of washout of the Cholecystectomy surgery site with Marcaine or pethidine solution on pain after laparoscopic cholecystectomy gallbladder surgery

Protocol summary

Summary

In this double blind clinical trial study, the effect of washout of the surgery site with Marcaine or pethidine on pain after laparoscopic cholecystectomy surgery of gallbladder will be evaluated. This study will be performed on 99 patients with gallbladder on bed and candidate for Laparoscopic Cholecystectomy in Velayat Hospital of Qazvin. In this study, patients are in ASA class I and II. Informed consent will be completed by patients, and who with sensitivity and allergy to Marcaine or petheidine or surgical complications are excluded. Patients were randomly divided into 3 groups on the basis of colored cards selection. After surgery, in the first group, the liver washout will be performed with 1.5% mg per kg of Marcaine diluted with 40 mL of saline normal; and in the second group will be performed with 0.5% mg per kg of pethedine diluted with 40 mL of saline; and in the third group will not make any infiltration. All three groups will be operated with the same surgical procedure. The postoperative pain will be assessed using a visual analog scale (VAS) at 1, 2, 4, 8, 16, 24 and 48 hours after surgery. For the VAS ≥ 4, patients treated with the usual narcotics such as 25 mg of pethidine by intravenous ampules. The required narcotic will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021632419N2**
Registration date: **2017-04-04, 1396/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-04, 1396/01/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Qazvin University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of washout of the Cholecystectomy surgery site with Marcaine or pethidine solution on pain after laparoscopic cholecystectomy gallbladder surgery

Public title

The effect of washout of the surgery site with Marcaine or petedine on postoperative analgesia in patients with gallbladder

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: a tendency to cooperate in the study and signed an informed consent form; Laparoscopic cholecystectomy surgery. Exclusion criteria: failure to discharge those with more than two days after Laparoscopic Cholecystectomy surgery; Marcaine or pethidine allergies; Class III and VI heart failure; Insufficiency of end Stage Renal Disease; Side effects of surgery; Open Cholecystectomy.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Shahid Bahonar Blvd., Qazvin
City
Qazvin
Postal code
Approval date
2017-02-14, 1395/11/26
Ethics committee reference number
IR.qums.rec.1395.281

Health conditions studied

1

Description of health condition studied
Gallstone
ICD-10 code
K82.0
ICD-10 code description
Occlusion of cystic duct or gallbladder without calculus

Primary outcomes

1

Description
Pain score after after the cholecystectomy surgery
Timepoint
After entering the recovery, during times of 1, 2, 4, 8, 16, 24 and 48 hours after surgery
Method of measurement
The patient will be trained on how to measure.The postoperative pain will be measured using the visual analogue scale (VAS).

Secondary outcomes

empty

Intervention groups

1

Description
In the first group, then prepare to surgery and immediately after cholecystectomy and before removing the trocar, the liver washout will be performed with 1.5% mg per kg of Marcaine diluted with 40 mL of saline solution.
Category
Treatment - Drugs

2

Description
In the second group, after the cholecystectomy, the liver washout will be performed with 0.5% mg per kg of pethedine diluted with 40 mL of saline normal.
Category
Treatment - Drugs

3

Description
In the third group will not make any infiltration.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat Educational and Treatment Center
Full name of responsible person
Dr. Mohammad mahdi Khazravi
Street address

Velayat Hospital, 22 Bahman Blvd., Minoodar Area, Qavin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Blvd., Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Science

Full name of responsible person

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Position

Resident of surgery

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Specialized surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty