

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 pethidine 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 pethidine 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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Name of organization / entity

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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 pethidine 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 pethidine 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
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Full name of responsible person
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Position
Resident of surgery

Other areas of specialty/work

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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