

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating of effect of infiltration of bupivacaine local anesthetic to port site in post-operative pain relief in laparoscopic cholecystectomy

Protocol summary

Summary

This double blind randomized clinical trial was performed on 60 patients with ASA I or II who were candidate for laparoscopic cholecystectomy in Velayat hospital in Qazvin of Iran. The age of patients ranged 20 to 70 years. Patients with history of diabetes, former bile ducts surgeries, sensitivity to local anesthesia drugs and addiction were excluded from the study. Patients were divided into case group (n: 30) and control group (n: 30) using randomized block design. Both groups received the same anesthesia method. In case groups; at the end of surgery before closing the surgical incision; 10 cc Bupivacaine 0.25% into two trocar sites(In each place 5 cc) were infiltrated. In control group; 10 cc normal saline into two trocar sites (In each place 5 cc) were infiltrated. Postoperative pain was recorded with the use of a visual analog scale at 1, 2, 4, 12 and 24 hours intervals after the surgery. Analgesia requirements and incidence of nausea and vomiting were also recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020632419N1**

Registration date: **2017-03-13, 1395/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

Name

Zahra Farahaninik

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3376 0620

Email address

z.farahaninik@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Qazvin University of Medical Sciences

Expected recruitment start date

2017-01-21, 1395/11/02

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating of effect of infiltration of bupivacaine local anesthetic to port site in post-operative pain relief in laparoscopic cholecystectomy

Public title

Evaluating of effect of infiltration of bupivacaine local anesthetic in post-operative pain relief in patients undergoing Laparoscopic Gallbladder Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients 20 to 70 years old; the category of America Society of Anesthesiology (ASA) are class 1 and 2; undergoing elective surgery laparoscopic cholecystectomy; consent to participate up to the end study. Exclusion criteria: patients with history of Diabetes; former bile ducts surgeries; sensitivity to local

anesthesia drugs; addiction.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be set in using randomized block design two groups (30 persons in case group and also 30 persons in control group).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Qazvin University of Medical Sciences

Street address

Qazvin, Shahid Bahonar Blvd

City

Qazvin

Postal code

Approval date

2017-01-20, 1395/11/01

Ethics committee reference number

IR.QUMS.REC.1395.278

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description

post operative pain

Timepoint

At 1, 2, 4, 12 and 24 hours after surgery

Method of measurement

According to VAS pain score systems

2

Description

nausea and vomiting

Timepoint

Every 1 hour during first 4 hours after transferring to the ward

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In case groups; at the end of surgery before closing the surgical incision; 10 cc Bupivacaine 0.25% into two trocar sites(In each place 5 cc) were infiltrated.

Category

Prevention

2

Description

In control group; at the end of surgery before closing the surgical incision; 10 cc normal saline into two trocar sites (In each place 5 cc) were infiltrated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat educational and treatment center

Full name of responsible person

Dr. Mehdi Hajizade

Street address

Velayat Hospital, 22 Bahaman Blvd, Minoodar district, Qazvin.

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Qazvin, Shahid Bahonar Blvd

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 of 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 Sciences

Full name of responsible person

Dr. Mehdi Hajizade

Position

Assistant of Surgery

Other areas of specialty/work**Street address**

Velayat Hospital, 22 Bahaman Blvd, Minoodar district, Qazvin.

City

Qazvin

Postal code**Phone**

+98 28 3376 0620

Fax**Email**

dr.mehdi.hajizadeh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Qazvin University Of Medical Sciences

Full name of responsible person

Dr. Zahra Farahaninik

Position

Assistant Professor of Surgery

Other areas of specialty/work**Street address**

Velayat Hospital, 22 Bahaman Blvd, Minoodar district, Qazvin.

City

Qazvin

Postal code**Phone**

+98 28 3377 0620

Fax**Email**

dr.zfarahaninik@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Zahra Farahaninik

Position

Associate Professor of surgery

Other areas of specialty/work**Street address****City**

Qazvin

Postal code**Phone**

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Fax**Email**

dr.zfarahaninik@gmail.com

Web page address

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