

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Study the effect of intraperitoneal bupivacaine on patient's pain relief after laparoscopic cholecystectomy

Protocol summary

Summary

This was a double blind randomized clinical trial which performed on 66 patients, ASA I, II who were candidate for laparoscopic cholecystectomy in Imam Reza Hospital, Kermanshah, Iran. The age of patients ranged 20-60 years. Patients with history of Diabetes, acute cholecystitis, heart ischemia, former bile ducts surgeries, addiction and sensitivity to local anesthesia drugs were excluded from the study. Patients were divided to two groups: target group and control group. Both groups received the same anesthesia method. Patients in target group were injected 20cc bupivacaine 0.25% (20cc vial, Merc Inc) in diaphragm right cavity at the beginning and at the end of operation but control group had no injection. Patients in both groups received 5cc bupivacaine 0.25% through all their incisions on the abdomen, it was the unique point of our study which made it different from all other studies. Patients' pain was assessed by VAS in both two groups every 1 hour for 4 hours after transferring to ward. Their nausea severity was assessed by VAS method too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810112946N1**

Registration date: **2010-05-25, 1389/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-25, 1389/03/04

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2009-11-22, 1388/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of intraperitoneal bupivacaine on patient's pain relief after laparoscopic cholecystectomy

Public title

Effect of intraperitoneal bupivacaine on pain relief after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA I, II patients who underwent laparoscopic cholecystectomy. Exclusion criteria: patients with history of Diabetes, acute cholecystitis, heart ischemia, former bile ducts surgeries, addiction and sensitivity to local anesthesia drugs.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **66****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences

Street address#2 building of medical university, Shahid beheshti
boulevard**City**

Kermanshah

Postal code**Approval date**

2009-03-19, 1387/12/29

Ethics committee reference number

23/j/14678/1

Health conditions studied**1****Description of health condition studied**

local anesthesia

ICD-10 code

Y40-Y59

ICD-10 code descriptionDrugs, medicaments and biological substances causing
adverse effects in therapeutic use**Primary outcomes****1****Description**

patient pain severity

Timepoint

every 1 hour for 4 hours after transferring to the ward.

Method of measurement

VAS

Secondary outcomes**1****Description**

patient's nausea severity

Timepointevery 1 hour during first 4 hours after transferring to the
ward**Method of measurement**

VAS

Intervention groups**1****Description**injecting 20cc bupivacaine in to diaphragm cavity in
intervention group**Category**

Treatment - Drugs

2**Description**

control group recieved nothing

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Dr. Mitra Yari

Street address**City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mitra Yari

Street address

Imam reza hospital, Parastar boulevard, Sorkhalijeh

City

Kermanshah

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

Kermanshah 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

Kermanshah university of medical sciences

Full name of responsible person

Dr. Mitra Yari

Position

Anesthesiologist and assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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