

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of shoulder pain after injection of Intrapleural Bupivacaine with Intraperitoneal Bupivacaine after laparoscopic cholecystectomy surgery

Protocol summary

Summary

Purpose: Comparison of shoulder pain after injection of Intrapleural Bupivacaine with Intraperitoneal Bupivacaine after laparoscopic cholecystectomy surgery. Design and criteria: This study is prospective, randomized, double blinded and clinical trial. 60 patients candidate for laparoscopic cholecystectomy surgery were chosen and divided randomly to 3 same groups. Inclusion criteria: Candidate for elective laparoscopic cholecystectomy; age over 18 years; ASA I-II; no history of lung disease; no history of motion sickness; no record of Addiction; no history of choledocholithiasis , Exclusion criteria: require open cholecystectomy; complicate surgery; incidence of adverse events intraoperative. Methods and intervention: we compared 3 group in this study group 1 without local anesthetic, group two 30cc marcaine 0.25% intrapleural, and group three 30 cc marcaine 0.25% intraperitoneal. Primary and secondary outcome: after surgery, the incidence of shoulder pain with VAS, in recovery room, 6 , 12 and 24 hours later and Paracetamol consumption and Diclofenac suppository dosage 24 hours after laparoscopic cholecystectomy surgery are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072712094N3**
Registration date: **2013-08-30, 1392/06/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-30, 1392/06/08

Registrant information

Name

Majid Razavi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 915 110 8630

Email address

razavim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2013-08-11, 1392/05/20

Expected recruitment end date

2013-10-12, 1392/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of shoulder pain after injection of Intrapleural Bupivacaine with Intraperitoneal Bupivacaine after laparoscopic cholecystectomy surgery

Public title

Shoulder pain after laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for elective laparoscopic cholecystectomy; age over 18 years; ASA I-II; no history

of lung disease;no history of motion sickness; no record of Addiction; no history of choledocholithiasis Exclusion criteria: require open cholecystectomy; complicate surgery; incidence of adverse events intraoperative

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi apartment, Daneshgah st, Mashhad

City

Mashhad

Postal code

Approval date

2013-06-08, 1392/03/18

Ethics committee reference number

910637

Health conditions studied

1

Description of health condition studied

cholecystectomic laparoscopic

ICD-10 code

K80.1

ICD-10 code description

Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description

shoulder pain

Timepoint

recovery room to 24 hours later

Method of measurement

Verbal analog scale(VAS)

Secondary outcomes

1

Description

Diclofenac suppository dosage

Timepoint

24 hours after surgery

Method of measurement

mili gram

2

Description

Paracetamol consumption

Timepoint

24 hours after surgery

Method of measurement

mili gram

Intervention groups

1

Description

intervention group 2 : intrapleural 30 ml of marcaine

0.25%

Category

Treatment - Drugs

2

Description

control group: not injection

Category

Treatment - Drugs

3

Description

intervention group 1 : intraperitoneal 30 ml of marcaine

0.25%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Majid Razavi

Street address

Department of Anesthesiology, Imam Reza Hospital,
Ibne Sina st, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of
Medical Science

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

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, Mashhad University of
Medical Science

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

Majid Razavi

Position

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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