Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 laparascopic

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

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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
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Assistant Professor

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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